

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

\_\_\_\_\_ X  
THE CITY OF HUNTINGTON, : Civil Action  
Plaintiff, : No. 3:17-cv-01362  
v. :  
AMERISOURCEBERGEN DRUG :  
CORPORATION, et al., :  
Defendants. :  
\_\_\_\_\_ X  
CABELL COUNTY COMMISSION, : Civil Action  
Plaintiff, : No. 3:17-cv-01665  
v. :  
AMERISOURCEBERGEN DRUG :  
CORPORATION, et al., :  
Defendants. :  
\_\_\_\_\_ X

BENCH TRIAL - VOLUME 14  
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE  
UNITED STATES DISTRICT COURT  
IN CHARLESTON, WEST VIRGINIA

MAY 20, 2021

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1                   PROCEEDINGS had before The Honorable David A.  
2                   Faber, Senior Status Judge, United States District  
3                   Court, Southern District of West Virginia, in  
4                   Charleston, West Virginia, on May 20, 2021, at 9:00  
5                   a.m., as follows:

6                   THE COURT: All right, Mr. Majestro.

7                   MR. MAJESTRO: I get the job of trying to change  
8                   your mind, Your Honor.

9                   THE COURT: Well --

10                  MR. MAJESTRO: Let me just --

11                  THE COURT: Have at it.

12                  MR. MAJESTRO: Let me just get right to it. The  
13                  ruling -- your ruling yesterday, which plaintiffs really  
14                  didn't have much time to prepare for consideration, we think  
15                  you should revisit for several reasons.

16                  First, and I've got a couple of cases that I want to  
17                  put up for you. The general rule is that a party has  
18                  discretion to determine the order of presentation -- more  
19                  rights. Thus, the fundamental rule universally accepted is  
20                  that with reference to facts whose relevancy depends on  
21                  others, the order of presentation is left to the discretion  
22                  of the party himself subject, of course, to the general  
23                  discretion of the Court.

24                  First -- First Circuit stated, certainly, the general  
25                  rule is that a party should be able to present his case and

1 order that case as he sees fit.

2 Second, Your Honor, this is especially true when we're  
3 dealing with issues of conditional relevancy. As the Fourth  
4 Circuit noted, Rule 104(b) continues the practice  
5 specifically authorizing the judge to admit the evidence  
6 subject to proof of the preliminary fact. And that's what  
7 we're intending to do here.

8 Third, Rule 703 governing experts states that experts  
9 can rely on inadmissible data. So, what we're proposing  
10 here is that -- is that the expert rely on data that is not  
11 only admissible, but that will be admitted later in the  
12 trial. Certainly, there's no prejudice for that.

13 Fourth, Your Honor, the plaintiffs are prejudiced by  
14 the ruling and this is the -- I think this is the most  
15 important point I'm making. Plaintiffs plan to prevent --  
16 present Mr. Rafalski first. He has been here for more than  
17 a week preparing and reviewing the defendants' testimony  
18 which will -- which will underlie his opinions. He is ready  
19 to go once the defendants' witnesses finish testifying.

20 Dr. McCann, on the other hand, went home. The  
21 attorneys that are responsible for presenting his testimony  
22 went home and they had not planned to have him prepared and  
23 ready next week.

24 The defendants' stipulation stipulated to splitting Dr.  
25 McCann's testimony up and that gave us a reasonable belief

1       that we would be able to present the order -- these  
2       witnesses in the order we wanted to.

3           In addition, this has a cascade effect on our other  
4       witnesses. By upending the schedule, we have a lot of  
5       experts who have other obligations. They're professionals,  
6       a lot of other witnesses that have other obligations, and it  
7       just totally completely causes problems with our scheduling  
8       of witnesses because it's not just scheduling the witnesses.  
9       Because of the way this case has worked, we have different  
10      lawyers responsible for different witnesses. We've got a  
11      schedule of lawyers.

12           In addition, this is what we believe -- the order we  
13       have presented we believe is the way that is the most  
14       persuasive to Your Honor. We ought to have a right to make  
15       that choice since it's our case to prove.

16           Next, Mr. Rafalski has issues. He is giving a  
17       deposition in Georgia on the 2nd and Judge Polster has just  
18       ordered him to give a deposition in the MDL on June -- on  
19       June 10th or June 11th. So, that's a -- those are more  
20       issues that we have to -- we have to work around.

21           Finally, the defendants' grounds don't have any merit.  
22       This is really a chicken and the egg problem. Mr.  
23       Rafalski's methods for determining suspicious orders were  
24       provided to Dr. McCann, who applied them to DEA's ARCOS data  
25       and the defendants' transactional data to determine the

1       number of orders that each method would have flagged.

2           Rafalski used McCann's calculations to provide for  
3       each method a table showing the number of dosage units of  
4       the oxycodone and hydrocodone the distributor shipped and  
5       the percentage of orders that would have been flagged based  
6       on the total units.

7           So, the testimony is interrelated. So, Dr. McCann is  
8       relying on Mr. Rafalski's methods. Mr. Rafalski is relying  
9       on Dr. McCann's calculations. For us to get that testimony  
10      in, both -- we have to have both of the testimonies. And  
11      so, which order it comes in, you're always going to have a  
12      situation where one expert is going to be conditionally  
13      relying on the other.

14           Finally, Your Honor, defendants' proposal is -- we  
15      think it gives the defendants a tactical advantage.  
16      McKesson and ABDC are parties in the Georgia case and  
17      they'll have the opportunity to depose Mr. Rafalski before  
18      he testifies in giving them a second shot at deposing him.

19           And the -- and for the same reasons we think it's best  
20      to present Mr. Rafalski first, the defendants would like to  
21      present Mr. McCann first. We would submit they don't get to  
22      make that choice. We've been very accommodating with them  
23      letting them do direct so their witness is in the middle of  
24      our case and we think we ought to have the discretion of how  
25      we call our experts.

1                   THE COURT: He's right, isn't he, Mr. Schmidt?

2                   MR. SCHMIDT: I think he's right, Your Honor, as  
3 to the general rule. The reason we raise this in this  
4 unique circumstance is because I think this circumstance is  
5 distinct. The general rule is, of course, that he gets to  
6 choose the sequencing.

7                   Here, we're talking about something very specific,  
8 though. We're talking about an expert who completely relies  
9 on the work of another expert where there's substantial risk  
10 of confusion in the record and just an unwieldy cross  
11 examination if we have to examine Mr. Rafalski on a  
12 methodology that Dr. McCann has employed without the Court  
13 having heard from Dr. McCann where we may be examining Mr.  
14 Rafalski on deposition transcripts from Dr. McCann.

15                  We're absolutely entitled to do that. That's what  
16 they're forcing.

17                  And I would point the Court to Rule 611. Rule 611  
18 regarding the mode and order of examining witnesses and  
19 presenting evidence leaves that to the control of the Court  
20 with the factors being avoiding waste of time, protecting  
21 witnesses from harassment or undue embarrassment, and make  
22 these procedures effective for determining the truth.

23                  In those circumstances we think it makes sense for Dr.  
24 McCann to come first so we don't have, first, an indirect  
25 examination through Dr. Rafalski, and then the same

1 examination through Dr. McCann himself where there's a  
2 potential for unwieldiness or confusion, but also  
3 contradiction.

4 As to the stipulation that we agreed to, we view that  
5 exactly the opposite way. We agreed with the plaintiffs  
6 that they could do something unusual with Dr. McCann, which  
7 is call him twice to try to facilitate this with the  
8 understanding that he would still be laying the predicate  
9 for Mr. Rafalski before Mr. Rafalski testified.

10 Now we're getting this very unusual out-of-sequence  
11 that we would never have agreed to where they can present  
12 Dr. McCann on the things they want, protect them on the  
13 things they don't want, and you'll recall, they actually  
14 objected when I started asking him about these methodologies  
15 and I made clear I wasn't going to get into them because I  
16 thought he was coming back before Dr. Rafalski would  
17 testify. They're presenting him in a way they they never  
18 could.

19 The guiding principle should be what's useful to the  
20 Court and what's useful to the record. That's what Rule 611  
21 says and, in these circumstances, we do think that calls for  
22 departure from the norm where we've already had that  
23 departure from the norm through the manner in which Dr.  
24 McCann has otherwise been presented.

25 The only other thing I will say as to the scheduling

1 conflict that they cite, it's very clear that, number one,  
2 that's of their own making. Dr. -- Mr. Rafalski was  
3 supposed to be deposed weeks ago. They told us a couple  
4 days before they didn't want us having a deposition of him  
5 before he testified, so they cancelled that in another case.  
6 That's not a legitimate ground for delaying here.

7 And, number two, the tactics there is naked in what  
8 they're saying. They want to avoid a second deposition  
9 before he testifies. That's a function of another case. We  
10 couldn't present to the Court their decision to cancel his  
11 deposition in another case when they did that. We're  
12 litigating that before the other court.

13 In the same way, they can't use that as a justification  
14 for this unusual procedure where they split up Dr. McCann's  
15 testimony and then have him actually come after the witness  
16 who is relying on him. Thank you, Your Honor.

17 THE COURT: I've given this a good bit of thought  
18 last night and I think the plaintiffs do have a right to  
19 control their case. It's obvious under the rules that they  
20 do, except under obvious circumstances, and I think the fair  
21 thing to do is reverse my ruling and allow the plaintiffs to  
22 proceed in the order they wish to proceed.

23 MR. SCHMIDT: We would simply ask then, Your  
24 Honor, for some leeway on cross examination to be able to  
25 explore what I think will end up being duplicative with

1       apologies, but necessitated by the sequencing that the  
2 plaintiffs have chosen.

3                 THE COURT: Well, we'll cross that bridge when we  
4 get to it, Mr. Schmidt, but I will keep that in mind.

5                 MR. SCHMIDT: Thank you, Your Honor.

6                 MR. MAJESTRO: Thank you, Your Honor. I'm off to  
7 prepare a witness. Excuse me.

8                 THE COURT: Mr. Mone.

9                 MR. FULLER: Your Honor, while he's coming up,  
10 Mike Fuller on behalf plaintiff. I would like to put on --  
11 excuses me, Judge -- put on the record an agreement that we  
12 worked out with the defendants as far as admission of some  
13 documents.

14                 THE COURT: Okay.

15                 MR. FULLER: And what we'll do is, they're going  
16 to review the entirety of the documents and then we'll  
17 provide the hard copies to the Court this afternoon, but by  
18 agreement, P-14290 --

19                 COURT REPORTER: I'm sorry. 14 --

20                 MR. FULLER: -- 290, 42071, 42100, 42102, 42103,  
21 42107, 42113, 42114, 42115, 42116, 42117, 42118, 42123,  
22 14288, 42432, and 14296 will be admitted by agreement after  
23 they've had a chance to review them, Judge, and we'll do  
24 that and get them on the record this afternoon.

25                 THE COURT: Ms. Mainigi?

1                   MS. MAINIGI: That's fine, Your Honor, after a  
2 conditional -- conditionally fine with that and we will  
3 review the thumb drive when we receive it, confirm, and  
4 we'll let the Court know by the afternoon.

5                   THE COURT: Okay. Well, I'm drowning in paper up  
6 here and I know it's going to get a lot worse before it's  
7 over.

8                   MR. FULLER: Well, Judge, most of those we'll put  
9 on a thumb drive to make it easier.

10                  THE COURT: Okay. Well, I'm technologically  
11 illiterate, Mr. Fuller. I don't know if I'll be able to  
12 handle that or not.

13                  Mr. Mone, you can resume the witness stand, sir, and  
14 you're still under oath, the oath you took yesterday to tell  
15 the truth.

16                  THE WITNESS: Yes, Your Honor.

17                  THE COURT: All right. Mr. Fuller, you may  
18 proceed.

19                  MR. FULLER: May it please the Court. I'm Mike  
20 Fuller on behalf of the plaintiffs.

21                  **CONTINUED DIRECT EXAMINATION**

22                  **BY MR. FULLER:**

23                  Q. Mr. Mone, yesterday, we were talking a little bit about  
24 your time and employment at Cardinal. Can you see this  
25 white board over here? Can you see that okay, Mr. Mone?

1       **A.**     Now it's white, yeah.

2       **Q.**     What we established is that you were at Cardinal over  
3                          the Anti-Diversion Department between the end of 2007  
4                          through 2012, right?

5       **A.**     Through September of 2012, yes.

6       **Q.**     All right. And around those same times, there are two  
7                          DEA actions against Cardinal, right?

8       **A.**     Prior to my arrival, there were two DEA actions.

9       **Q.**     Well, and just prior to your arrival in December, there  
10                         were two administrative inspection warrants and ISOs,  
11                         correct?

12      **A.**     I do not know about the administrative inspection  
13                         warrants. I'm aware that there were two, prior to my  
14                         arrival, ISOs.

15      **Q.**     Very good. And, in 2012, right before you left, was  
16                         another Immediate Suspension Order for the Lakeland  
17                         Distribution Center, right?

18      **A.**     That is correct.

19      **Q.**     And prior to your arrival, it was a Mr. Reardon that  
20                         was over Anti-Diversion, correct?

21      **A.**     Yes.

22      **Q.**     And are you aware who was there after your departure in  
23                         September of 2012? And when I say your departure, let's  
24                         make it clear. Your departure from that department, okay?

25      **A.**     Mr. Todd Cameron.

1       **Q.**   And so, you're in this middle section, right?

2       **A.**   I am.

3       **Q.**   And for ease, I'll refer to this as Chapter 1, which is  
4 prior to your arrival in that department, okay?

5       **A.**   All right.

6       **Q.**   Chapter 2, which is your time frame, right?

7       **A.**   Right.

8       **Q.**   And then Chapter 3 will be after your departure and Mr.  
9 Todd Cameron's arrival, correct?

10      **A.**   Fair enough.

11      **Q.**   Okay. Now, I believe you testified yesterday --

12            MR. FULLER: Can I get 8861 and don't put it on  
13 the screen yet.

14            May I approach the witness, Your Honor?

15            THE COURT: Yes.

16            BY MR. FULLER:

17      **Q.**   I believe you testified yesterday related to -- what we  
18 refer to as the Rannazzisi letters; do you recall that?

19      **A.**   That's the December of 2007 Joe letter, yes.

20      **Q.**   And you're aware that there was an earlier letter in  
21 2006, correct?

22      **A.**   I have no personal knowledge of a prior 2006 letter.

23      **Q.**   Okay. I've handed you a document which is marked 8861,  
24 correct?

25      **A.**   It is.

1       **Q.**     And do you recognize that document? Well, actually,  
2 let me start. What is it?

3       **A.**     It's an e-mail from Bob Giacalone to other members of  
4 both the -- our team, as well as outside legal counsel.

5       **Q.**     And who is -- you say Bob Giacalone. It actually says  
6 Robert Giacalone, right?

7       **A.**     Yes.

8       **Q.**     But you call him Bob; is that fair?

9       **A.**     I do.

10      **Q.**     And who is Mr. Giacalone?

11      **A.**     Mr. Giacalone was the Senior Vice President of Cardinal  
12 Health's Legal Regulatory Group.

13      **Q.**     Is he someone that you worked with on a regular basis  
14 when you were in that -- that position, what we call Chapter  
15 2?

16      **A.**     I did work with Bob, yes.

17      **Q.**     Okay. And are you a recipient of this e-mail?

18      **A.**     I am.

19      **Q.**     And does it appear that there are attachments to this  
20 e-mail?

21      **A.**     It does.

22      **Q.**     And is there any reason to believe that you wouldn't  
23 have received these in your regular course of employment  
24 there at Cardinal because the e-mail was sent to you?

25      **A.**     I see no reason why I wouldn't have received it.

1       **Q.**   And can you take a look at the attachments? Does the  
2 first attachment appear to be a letter from the DEA to  
3 Cardinal Health, Zanesville, Ohio from February 7th of 2007?

4       **A.**   Yes.

5       **Q.**   Does the second letter appear to be to Cardinal Health  
6 on December 27th, 2007?

7       **A.**   To the Syracuse Distribution Center, yes.

8       **Q.**   Sir, and is it your understanding that each of the  
9 distribution centers received a Rannazzisi letter or do you  
10 know?

11      **A.**   I have -- I have no independent knowledge of whether  
12 each of the distribution centers received it, but it is more  
13 than likely that they did.

14      **Q.**   Fair enough. The next document attached there is  
15 Diversion Investigators Manual, correct?

16      **A.**   It is. It appears -- it's a letter to Cardinal Health  
17 to Bob, the subject of which is the Diversion Investigators  
18 Manual.

19      **Q.**   And it has an excerpt from the Diversion Investigators  
20 Manual; is that right?

21      **A.**   It does.

22      **Q.**   And if you turn to the next document, it's a memorandum  
23 that has DEA letterhead prepared by Linden Barber?

24      **A.**   Correct, from March 1st of 2007.

25      **Q.**   Yes, sir. And then you have -- the last document is

1                   September 27th, 2006, a letter from Joe Rannazzisi, correct?

2                   **A.**     And that is in this packet, that is correct.

3                   **Q.**     And, Mr. Mone, you would have received this in the  
4 regular course of your employment with Cardinal?

5                   **A.**     To the best of my knowledge, since I am on this as a  
6 cc, I would have received it.

7                   MR. FULLER: Your Honor, I would submit and move  
8 Plaintiffs' Exhibit 8861 into evidence.

9                   MS. MAINIGI: Your Honor, objection for several  
10 reasons to this compilation. First, this was not identified  
11 to us in the proper course. It was identified after our  
12 7:00 p.m. deadline.

13                  But leaving that aside, it includes several documents  
14 that are hearsay and there's several Joe Rannazzisi letters  
15 in here. I think Mr. Mone several times has been approached  
16 by Mr. Fuller yesterday and today now about earlier versions  
17 of a Rannazzisi letter. Mr. Mone testified he did not begin  
18 in his role until December, 2007 and that he did not see  
19 earlier versions of the letter.

20                  I believe Your Honor admitted the Rannazzisi letters in  
21 the ABDC witness case for the limited purpose that it bears  
22 upon notice, but subject to the existing hearsay objections.  
23 Mr. Mone was not actually in his role at Cardinal either for  
24 receipt of the December, 2006 letter, nor for receipt of the  
25 February, 2007 letter.

1           So, the documents right now, a foundation has not been  
2 laid for them and they are not documents that ought to be  
3 coming in through Mr. Mone. Mr. Fuller can use another  
4 witness to do that.

5           MR. ACKERMAN: Your Honor, with respect to each of  
6 those in turn, I'll start with the foundation first.

7           MS. MAINIGI: Your Honor, I'm sorry to interrupt,  
8 but I do not think it is proper for Mr. Ackerman -- we have  
9 someone who is taking testimony in the form of Mr. Fuller.  
10 It is not proper for Mr. Ackerman to handle all of these  
11 objections.

12           THE COURT: Well --

13           MR. ACKERMAN: Your Honor, we're --

14           THE COURT: I agree with that. I let this go on  
15 because there wasn't any objection to it, but the rule is  
16 one lawyer per witness per party and if there's an objection  
17 to me allowing otherwise, then I'm going to sustain the  
18 objection.

19           Mr. Fuller, you can talk to Mr. Ackerman if, you want  
20 to.

21           MR. ACKERMAN: Your Honor, we've done it this way  
22 to try to expedite the trial so that we don't have to have  
23 conversations for each objection. If we have to do it that  
24 way, we will --

25           MS. MAINIGI: Your Honor --

1                   MR. ACKERMAN: But it is certainly within your  
2 discretion.

3                   MS. MAINIGI: Your Honor, Mr. Fuller has been  
4 preparing for this testimony for days and days and days.  
5 None of this is a surprise in terms of the issues that are  
6 going to arise.

7                   THE COURT: Okay. From now on, unless there's  
8 some exceptional reason not to do that, it's one lawyer per  
9 witness per party and that's the rule and if any party in  
10 the case insists upon me applying it that way, that's what  
11 I'm going to do unless there's a specific reason in the  
12 context of not doing it that way.

13                  MR. ACKERMAN: Your Honor, isn't that what we're  
14 doing? We have two plaintiffs. We have two separate  
15 parties.

16                  MS. MAINIGI: There is one -- yes, there are two  
17 plaintiffs, but there is one attorney taking testimony right  
18 now. That is the attorney who is trying to get in documents  
19 to which I've objected. That's the attorney who should  
20 respond.

21                  MR. ACKERMAN: Well, give me a minute to confer  
22 with Mr. Fuller, Your Honor.

23                  (Pause)

24                  MR. FULLER: So, Your Honor, just as they were  
25 admitted with ABDC, this shows notice and knowledge. Mr.

1 Mone testified that he didn't have any recollection or  
2 didn't remember. This clearly -- this document shows he got  
3 these documents. He was on the e-mail. He received them.  
4 I'm fine not questioning him about them.

5 THE COURT: Okay. Can I receive them for the  
6 limited purpose of showing notice and knowledge of the  
7 corporation, Ms. Mainigi, and not admit them for the truth  
8 of the matter asserted?

9 MS. MAINIGI: Your Honor, not as it relates to the  
10 December, 2006 and the February, 2007 letter. The idea that  
11 Mr. Mone got them in 2012 is no notice at all for receipt in  
12 2006 and February of 2007, which is what I believe Mr.  
13 Fuller hopes to establish.

14 He can do it through another witness. He has other  
15 witnesses that -- that he can establish that through, but  
16 Mr. Mone has made clear that he didn't arrive in this role  
17 until December, 2007.

18 MR. FULLER: Judge --

19 THE COURT: How much of this do you object to, the  
20 whole packet?

21 MS. MAINIGI: We're fine with the December, 2007  
22 letter, Your Honor. We're fine with the same -- we're fine  
23 for admission for notice purposes with the December, 2007  
24 letter.

25 THE COURT: And the rest of it you object to; is

1           that right?

2           MS. MAINIGI: Correct, Your Honor.

3           THE COURT: I'm going to admit the December, 2007  
4 letter, Mr. Fuller, and sustain the objection with regard to  
5 the rest of it.

6           **PLAINTIFF EXHIBIT 8861 ADMITTED**

7           THE COURT: Mr. Hester?

8           MR. HESTER: Your Honor, may I just have  
9 clarification it's not being admitted for the truth of the  
10 matter asserted; it's being admitted for the fact that the  
11 statement was made?

12          THE COURT: That's right. It's admitted for the  
13 limited purpose stated.

14          MR. FULLER: Judge, these documents are also on a  
15 stipulation with the defendants and so I think they should  
16 be admitted. Maybe I can't use them with Mr. Mone.

17          THE COURT: If I understand the stipulation, that  
18 gets around the authentication rule, but it doesn't get  
19 around any other objections; is that correct?

20          MS. MAINIGI: That's correct, Your Honor.

21          THE COURT: And so, you've authenticated them  
22 through the stipulation, but that doesn't get you around the  
23 hearsay problem and any other evidentiary problem.

24          MR. FULLER: Sure, Judge.

25          MS. MAINIGI: And just for the record, I think as

1       it relates to these particular letters, we did stipulate as  
2       to authenticity, but -- but the foundation has -- we made  
3       clear that the foundation needs to be laid.

4                  THE COURT: All right. Well, I made my ruling on  
5       this.

6                  Go ahead, Mr. Fuller.

7                  And this doesn't mean they're out absolutely forever.  
8       If you have another witness that can do it right --

9                  MR. FULLER: Well, Judge --

10                 THE COURT: You can feel free to go forward with  
11       that.

12                 MR. FULLER: Sure. Here's the problem, Judge.  
13       These -- and I'll go back to the board of setting out the  
14       time frames.

15                 MR. FARRELL: Excuse me, Judge. Can I confer with  
16       Mr. Fuller?

17                 THE COURT: Yes.

18                 (Pause)

19                 MR. FULLER: Hey, Judge, can we take a brief  
20       recess?

21                 MS. MAINIGI: Your Honor -- that's fine.

22                 THE COURT: Well, yes. I think Mr. Fuller has  
23       been surprised by all of this and we'll be in recess.

24                 Can you do it in five minutes, Mr. Fuller?

25                 MR. FULLER: Sure, Judge.

1                   THE COURT: Okay. Ms. Mainigi wanted to say  
2 something and I'm going to let you say it. Go ahead.

3                   MS. MAINIGI: Sorry, Your Honor. These -- I don't  
4 -- with all due respect, I do not think Mr. Fuller was  
5 surprised. He has known this is coming. He sent these at  
6 10:00 last night. This has been an ongoing back and forth.  
7 There's no surprise here.

8                   THE COURT: Okay. Well, I'll indulge him this  
9 time.

10                  MR. FULLER: Thank you, Your Honor.

11                  THE COURT: Five minutes.

12                  (Recess taken)

13                  MS. MAINIGI: Your Honor, the one thing that I  
14 would say --

15                  LAW CLERK: Please be seated and come to order.

16                  MS. MAINIGI: I'm sorry. The one thing I would  
17 add is to the extent they want to use the letters as notice  
18 in 2012 to Mr. Mone, I'm fine with that, and I apologize if  
19 I was not clear on that.

20                  My understanding is the whole purpose of trying to get  
21 them in right now is to establish notice to the company or  
22 to Mr. Mone in 2006 and I just don't think they can overcome  
23 what they need to overcome with this particular witness for  
24 2006. But to the extent they would like to establish notice  
25 as of 2012, we're fine with that.

1                   THE COURT: Mr. Farrell?

2                   MR. FARRELL: Judge, may I make a proffer for the  
3 Court in the absence of the witness?

4                   THE COURT: Yes.

5                   MR. FARRELL: During discovery we served a  
6 subpoena for the Apex deposition of each of the defendants.  
7 It was --

8                   THE COURT: What's an Apex deposition?

9                   MR. FARRELL: Their boss. The three people that  
10 testified at Congress in the ENC Report, we served subpoenas  
11 on or, through the discovery process, if they were still  
12 employed, we asked for their deposition. The Apex Doctrine  
13 means there's certain elements you have to fulfill before  
14 you take a CEO.

15                  It was appealed to a special master. Special master  
16 ruled in our favor and, if I recall, it was appealed to you  
17 and the appeal, we prevailed.

18                  We also served a 30(b) (6) notice on each of the three  
19 defendants for this trial and that 30(b) (6) notice, the  
20 contents included laying the foundation for documents. Sir,  
21 I know because I wrote it.

22                  We then engaged in discussions, me personally, Paul  
23 Farrell, as an officer of the court, and I spoke with each  
24 of my learned counsel and we reached an accommodation and a  
25 stipulation that is set forth in Document 835 with Cardinal

1 Health. The document is virtually identical with each of  
2 the three defendants.

3 ECF 835 with Cardinal Health starts with Paragraph  
4 number 1 where, on behalf of the City of Huntington and  
5 Cabell County, we agreed not to call George Barrett, the  
6 CEO, or Linden Barber, their counsel, to testify at trial.  
7 Cardinal Health reserved the right to do so in their case in  
8 chief, but we forfeited that right with the stipulation.

9 Paragraph 2, we even went to the state court litigants  
10 and got the state court litigants to agree to stand down on  
11 the CEO deposition of George Barrett.

12 Number three, and I'd like to read this into the  
13 record. "The CT2 plaintiffs will not take any further fact  
14 depositions of Cardinal Health witnesses in connection with  
15 CT2. The CT2 plaintiffs will withdraw their Rule 30(b)(6)  
16 notice to Cardinal Health and inform the Court the motion to  
17 enforce that notice is moot as to Cardinal Health.

18 So, let me be as crystal clear and blunt as I can. We  
19 stood down on discovery on August 6th, 2020 in exchange for  
20 this stipulation. This stipulation goes on to say that --  
21 this stipulation goes on to say that they will not object on  
22 authentication grounds, but that's not where they rested.

23 They also said they will not object to sponsoring  
24 witness. And, to be clear, in the -- in Page 3 of ECF 835,  
25 it says that if there is -- let me read it. "The plaintiffs

1 have expressed a desire to, as much as possible, negate the  
2 need for plaintiffs to bring multiple Cardinal Health  
3 witnesses to trial for the sole purpose of authenticating  
4 and establishing the proper foundation for use of the  
5 identified documents at trial." That's number one.

6 "The parties will work in good faith to address  
7 specific issues relating to authenticity and foundation  
8 between now and trial." That's the only thing that's said  
9 about before trial. We didn't agree to work this out. We  
10 said we'd negotiate in good faith.

11 And then this is the sentence that I'd like to bring  
12 emphasis to. "Plaintiffs will be provided an opportunity to  
13 cure all unresolved issues relating to authenticity and  
14 foundation, including the ability to depose and/or call a  
15 custodial witness at trial."

16 Judge, the document that they just objected to is set  
17 forth specifically in Appendix A as an identified document  
18 for us to present at trial and if they're going to be -- if  
19 they're going to insist on the breach of this, then we'll  
20 declare it breached and we will begin calling custodial  
21 witnesses, and we will issue a trial subpoena for their CEO.

22 So, this is -- I understand the point about not asking  
23 a witness about a document. We're not asking for that.  
24 We're trying to admit the core elements of our case with  
25 documents that inculpate the defendants, in our humble

1                   opinion, and they're -- the defendants reached an agreement  
2                   with us of the entry of these documents in the record and  
3                   now they're objecting.

4                   THE COURT: Okay. Let me hear from Ms. Mainigi.

5                   MS. MAINIGI: Your Honor, I don't think we should  
6                   distract from getting this witness back on the stand, but we  
7                   did agree to authenticity, but as I got up and said just  
8                   now, Your Honor, the notice -- and we've agreed to notice,  
9                   but the notice is as of 2012. The e-mail as of 2012. So,  
10                  if there's any notice to be established, it is notice as of  
11                  2012.

12                  Ultimately, they chose which witnesses they wanted to  
13                  bring. They twice cancelled Mr. Mone's deposition in the  
14                  MDL. They had an opportunity to depose him. We had him  
15                  ready to go. They decided for strategic reasons to cancel  
16                  his deposition.

17                  They also, as you see from the chart that Mr. Fuller  
18                  has put up there, Steve Reardon, they have depo designations  
19                  on Steve Reardon. And I think the depo designations -- I  
20                  can go back and check, but I think they include testimony  
21                  related to a December, 2006 letter.

22                  So, there is no reason to get off track here with Mr.  
23                  Mone, who has clearly specified when he's there. If they  
24                  want to take this up with us later, we're happy to continue  
25                  having a conversation to see what we can work out, but this

1       is not the witness or the vehicle to -- to ask questions  
2       about December, 2006.

3           So, we're happy to continue chatting with them and  
4       figuring out if we're disagreeing about the stipulation or  
5       whether there's something we can work out vis-a-vis the  
6       stipulation, but this is not the witness to ask questions  
7       about a December, 2006 letter.

8           THE COURT: Well, are you going to question this  
9       witness about the time period that he wasn't there?

10          MR. FARRELL: No, Judge. What we -- what we would  
11       expect is for your rulings to be consistent. If the witness  
12       has no personal knowledge, then that's one thing. This is  
13       about the admission of documents, evidence, into the record  
14       for purposes of findings of fact and conclusions of law.

15          This isn't -- if the witness has no knowledge, you've  
16       made it clear you can't specify to it, but we have the -- we  
17       have agreed to live witnesses and we need to use those live  
18       witnesses as a vehicle to enter documents into the record.  
19       That's it.

20          MS. MAINIGI: Your Honor, he still has to get over  
21       the other objections. He has to get over hearsay. And so,  
22       to get over hearsay, all he has is notice as of 2012. This  
23       document, which is the one they're relying on, is a 2012  
24       document with attachments.

25           So, if they want to use this 2012 document and get it

1 admitted for a limited purpose as an exception to the  
2 hearsay rule, it is notice as of 2012. That is why I  
3 amended my statements earlier. So, this notice as of 2012,  
4 but that is the proper application of the stipulation.

5 THE COURT: The cover memo says -- or e-mail says,  
6 "Per your request, please see the attached DEA guidelines.  
7 In going through my files, I've included an excerpt", and  
8 then he goes on to talk about the documents.

9 I'm going to let it in. Objection is overruled. It's  
10 in.

11 MR. HESTER: But, Your Honor, may I have  
12 clarification? I believe the prior ruling was that you had  
13 admitted it for the purpose of the fact the statement was  
14 made, not for the truth, and there was no -- there was no  
15 waiver of the hearsay objection in these stipulations. So,  
16 I just wanted to be clear on the basis for the Court's  
17 admission.

18 THE COURT: I'm, at this point, admitting it for  
19 the limited purpose of showing notice and knowledge of the  
20 corporation for the whole time period covered by the  
21 documents, but I'm not admitting it for the truth of the  
22 matter asserted insofar as there's hearsay that the  
23 plaintiffs have not gotten around by showing that there's an  
24 exception.

25 MS. MAINIGI: Thank you, Your Honor.

1           And just so I don't interrupt later, I assume Mr.  
2 Fuller still has to establish foundation if he wants to  
3 question on it.

4           THE COURT: All right. Go ahead, Mr. -- can we  
5 get Mr. Mone back here?

6           MR. FULLER: I'll ask the questions, but I don't  
7 know that I'll get answers until he's back, Judge.

8           THE COURT: Please resume the witness stand, Mr.  
9 Mone.

10          Go ahead, Mr. Fuller.

11          MR. FULLER: Thank you, Your Honor.

12          BY MR. FULLER:

13          **Q.** Mr. Mone.

14          **A.** Yes, sir.

15          MR. FULLER: 1983.

16          BY MR. FULLER:

17          **Q.** I think when we were talking yesterday, you recollect  
18 that there were distributor initiatives, distributor  
19 briefings.

20          MR. FULLER: May I approach the witness, Your  
21 Honor?

22          THE COURT: Yes.

23          BY MR. FULLER:

24          **Q.** Mr. Mone, I've provided you with a document -- well,  
25 let me ask you before you look at it -- provided you -- the

1 distributor initiative, were you ever provided a copy of  
2 what Cardinal got in these distributor briefings?

3 **A.** To the best of my recollection, I was not.

4 **Q.** So, you were brought in and asked to revamp the SOM  
5 system, but you weren't provided the briefing information  
6 that the DEA left Cardinal back in 2005 or 2006?

7 **A.** When I was brought in, I was asked to continue --

8 THE COURT: Just a minute, Mr. Fuller.

9 MR. FULLER: Yes, Your Honor.

10 (Pause)

11 THE COURT: All right, Mr. Fuller.

12 BY MR. FULLER:

13 **Q.** All right. Go ahead, Mr. Mone.

14 **A.** When I was brought in, I was asked to continue the  
15 enhancements and -- of the existing system that was in  
16 place.

17 **Q.** And I'm assuming then that you didn't review any of the  
18 guidance provided by the DEA to Cardinal; is that right,  
19 related to the distributor briefings?

20 **A.** What I testified to is I don't recall seeing any of the  
21 documents that were part of the prior -- before my time, the  
22 2005-2006 distributor initiative.

23 **Q.** And you have a document in front of you. Do you  
24 recognize it?

25 **A.** I do not.

1       **Q.**   Does it -- the first page is an e-mail; is that  
2           correct?

3       **A.**   It is.

4       **Q.**   And who is on the e-mail?

5       **A.**   It is from Robert Giacalone on 6/1 of 2007 to Steve  
6           Reardon.

7       **Q.**   And Mr. Reardon, as we discussed, prior to your  
8           arrival, was in charge of Anti-Diversion?

9       **A.**   He was.

10      **Q.**   And Robert Giacalone, what was his position?

11      **A.**   He was the Senior Vice President of Regulatory.

12      **Q.**   And, if you will, flip through the document. Do you  
13           recognize what the document is?

14      **A.**   I do not recognize the PowerPoint slides.

15           THE COURT: You've already asked him that and he's  
16           answered it. He said he didn't recognize it and you asked  
17           him again and he said he didn't recognize it again, Mr.  
18           Fuller.

19           MR. FULLER: Yes, Your Honor. Now I'm going to  
20           move in Plaintiffs' Exhibit 1983. It has been stipulated,  
21           like the last document, between the parties. I'm not going  
22           to question the witness about it, but I just want it in for  
23           purposes of the record.

24           MR. HESTER: Your Honor, we would object on  
25           hearsay grounds to the document that's appended to the

1 e-mail. It's full of hearsay and I think the Court has  
2 previously admitted a prior -- another version of this same  
3 packet only for the fact that the statement was made not for  
4 the truth of the matter asserted.

5 THE COURT: Ms. Mainigi?

6 MS. MAINIGI: Your Honor, I would also object on  
7 -- on hearsay grounds. We're certainly okay with notice if  
8 they would like to admit it for the purpose of notice and I  
9 will note, once again, for the record, that Mr. Reardon has  
10 designations. Mr. Reardon, who came before Mr. Mone, has  
11 depo designations that may cover what they would like.

12 THE COURT: Mr. Hester, may I admit it for the  
13 limited purposes?

14 MR. HESTER: Yes, Your Honor. We have no  
15 objection as long as it's admitted for that limited purpose.

16 THE COURT: Mr. Nicholas?

17 MR. NICHOLAS: No objection.

18 THE COURT: All right. It's admitted for the  
19 limited purpose of showing knowledge of the defendant  
20 Cardinal; is that right? Did that get it?

21 MS. MAINIGI: Yes, Your Honor.

22 MR. FULLER: Thank you, Your Honor.

23 **PLAINTIFF EXHIBIT 1983 ADMITTED**

24 MR. FULLER:

25 Q. Next, Mr. Mone, we talked about the MOUs and MOAs. You

1 have a recollection of those, correct?

2 **A.** I do.

3 MR. FULLER: 8873.

4 BY MR. FULLER:

5 **Q.** Mr. Mone, do you recognize this document?

6 **A.** I do not.

7 **Q.** Do you recognize individuals on the document?

8 **A.** I'm sorry?

9 **Q.** Do you recognize the individuals on the document?

10 **A.** I do.

11 **Q.** Is that Mr. Giacalone again?

12 **A.** It is from Mr. Robert Giacalone on January 25th of  
13 2016.

14 **Q.** And there are some attachments to this document; is  
15 that correct?

16 **A.** It's a rather large packet, so yes, there are  
17 attachments.

18 **Q.** And if you look, there are some of the Rannazzisi  
19 letters. If you will turn to Page 15, and if you look at  
20 the bottom, there's page numbers down there?

21 **A.** Yeah.

22 **Q.** See if you recognize that document.

23 **A.** The -- the Page 15 is a cover page for a 2012 DEA MOA.

24 **Q.** And are you familiar with that document?

25 MS. MAINIGI: Objection, Your Honor. Yesterday

1       there were some questions that I did not object to at all  
2       related to the 2008 action and the 2012 action, but it seems  
3       that Mr. Fuller is looking for admission of these documents,  
4       as well as to gain testimony related to those two actions,  
5       and we've got a number of objections.

6           We've got a hearsay objection, but we have also a  
7       personal knowledge objection with respect to Mr. Mone, and  
8       then we've got a geographic scope objection. Both of these  
9       actions have nothing to do with West Virginia.

10          The 2008 action relates to four distribution centers  
11       outside of West Virginia. The 2012 action relates to one  
12       Distribution Center in Florida, as well as four pharmacies  
13       in Florida. So, there is absolutely no demonstrable nexus  
14       to Cabell-Huntington and no other aspects of the tests that  
15       you have laid out for geographic scope is met either, Your  
16       Honor.

17           And just for the purpose of the record, we also reserve  
18       our objections on motion in limine to the Court.

19           THE COURT: Mr. Fuller?

20           MR. FULLER: Yes, Your Honor, if I might, let me  
21       lay a little more of a predicate, if it's okay with the  
22       Court.

23           THE COURT: All right. Go ahead.

24           BY MR. FULLER:

25           Q.     Mr. Mone --

1                   THE COURT: I'll reserve ruling on the objection.

2 Go ahead.

3                   MR. FULLER: Thank you, Judge.

4                   BY MR. FULLER:

5           **Q.** Mr. Mone, the system that you put in place, was it  
6 limited to any geographical area within the United States?

7           **A.** The system that was put in place was a system that was  
8 designed to identify and report suspicious orders for any  
9 customer of Cardinal Health.

10          **Q.** Any customer in the country, right?

11          **A.** That is correct.

12          **Q.** Shipping out of any Distribution Center, correct?

13          **A.** That is correct.

14          **Q.** So, it was a centralized system run out of Dublin,  
15 Ohio, correct?

16          **A.** It was a centralized system that involved the  
17 individual orders for individual pharmacies by individual  
18 distribution centers.

19          **Q.** Operated out of Dublin, Ohio, correct?

20          **A.** The operation of the assessment was done in Dublin,  
21 Ohio.

22          **Q.** You had an electronic system that was maintained in  
23 Dublin, correct?

24          **A.** I'm going to assume that the computers were in Dublin.  
25 I don't know where the computers were, but the technology --

1           the team was in Dublin.

2       **Q.**   The team?

3       **A.**   The immediate team. It expanded into the distribution  
4           centers, as well, but with the office.

5       **Q.**   And then, when you arrived in December of 2012, the  
6           system that you were revamping was also a nationally based  
7           system based on what's called Ingredient Limit Reports,  
8           correct?

9       **A.**   Well, I have to correct you when I arrived. I arrived  
10          in 2007, not 2012.

11      **Q.**   I'm sorry. In December of 2007.

12      **A.**   It was a system that was -- the system that was in  
13          place when I arrived was a -- a migration from the ILR  
14          system into -- we had already begun the process of  
15          integrating into a new electronic system.

16      **Q.**   And the ILR system was a nationally based system,  
17          correct?

18      **A.**   The ILR system -- the ILR system occurred at the  
19          distribution centers.

20      **Q.**   But it was the same system across the country, right?  
21          Each Distribution Center ran an ILR and submitted those on a  
22          monthly basis; is that correct?

23      **A.**   My understanding is that each individual Distribution  
24          Center ran their own reports and submitted those to the Drug  
25          Enforcement Administration. I do not know whether anything

1 occurred centrally.

2 **Q.** And Mr. Reardon ran that program; is that right?

3 **A.** Mr. Reardon was in charge of that program.

4 **Q.** Mr. Reardon and his team was based in Dublin, Ohio,  
5 correct?

6 **A.** Mr. Reardon's office was in Dublin, Ohio.

7 MR. FULLER: Your Honor, I think I've now laid the  
8 predicate that these are national systems.

9 THE COURT: Ms. Mainigi?

10 MS. MAINIGI: I disagree, Your Honor. I think we  
11 just heard testimony -- as it relates to the 2008, I think  
12 we just heard testimony from Mr. Mone that they were run out  
13 of the distribution centers. The 2008 action related to  
14 Auburn, Washington; Lakeland, Florida; Swedesboro, New  
15 Jersey; and Stafford, Texas. There was nothing that related  
16 to Cabell-Huntington. There is a Distribution Center in  
17 Wheeling, West Virginia that was not part of the 2008  
18 action.

19 If I go back, Your Honor, to -- to the test you laid  
20 out that the plaintiffs have to meet in order to get in  
21 evidence beyond Cabell-Huntington, they first need to show a  
22 demonstrable nexus to Cabell-Huntington. These two MOUs  
23 have no demonstrable nexus to Cabell-Huntington. I don't  
24 think they would dispute that.

25 Second, they could show national trends in shipment.

1 MOUs would not show any national trends in shipment. Third,  
2 systemic failure. If they are trying to say that these  
3 isolated MOUs that occurred in first four, and then one  
4 Distribution Center well far away from Cabell-Huntington,  
5 when there are 27 distribution centers that Cardinal has all  
6 over the country, that somehow that's evidence of some  
7 failure in Cabell-Huntington, that's absolutely wrong.

8 There's no way that distribution centers that don't  
9 service Cabell and Huntington in any way, shape or form that  
10 were implicated in those MOUs could somehow demonstrate some  
11 systemic failure that affected Cabell-Huntington.

12 If they want to show that the system was faulty, then  
13 we ought to see some evidence of that in Cabell-Huntington  
14 and we welcome them putting on some evidence of that in  
15 Cabell-Huntington, but bringing in settlement agreements  
16 that have nothing to do with Cabell-Huntington is just a  
17 complete waste of time and contrary to what Your Honor has  
18 ruled.

19 THE COURT: It looks to me like, I mean, the -- it  
20 is arguably relevant to whether or not there is a systemic  
21 failure. I think it is a -- this goes to the weight rather  
22 than the admissibility on that issue and -- and I am going  
23 to let it in as it relates to the issue of the systemic  
24 failure.

25 The system was designed to cover all of the operations

1       here and it broke down in a couple of instances that were  
2       far removed apparently from Cabell-Huntington, but it does  
3       relate to the overarching issue of the systemic failure to a  
4       certain extent and I'll consider it insofar as it's relevant  
5       to that.

6           Mr. Hester?

7           MR. HESTER: Your Honor, again, we have a hearsay  
8       objection to this. We understand that the statement was  
9       made, and -- but we would object to its introduction for the  
10      truth of the matter asserted.

11          MS. KEARSE: And, Your Honor, I think -- I know  
12      I've been sitting quietly, but I think we have an objection  
13      --

14          COURT REPORTER: I'm sorry. I'm having a hard  
15      time hearing you.

16          MS. KEARSE: I'm sorry. I'm used to having my  
17      mask on.

18          Anne Kearse, Your Honor. I've been sitting here  
19      quietly, but I would like to invoke the same rule. We have  
20      one witness, one person who is objecting, and one person who  
21      is defending this witness. This is a Cardinal discussion  
22      right now. We have McKesson raising objections, as well.

23          So, I would like to object and say we have the same  
24      rule we have now, one lawyer, one witness defending --

25          THE COURT: Well, I think one lawyer for each

1 party with regard to each witness.

2 MR. KEARSE: Yeah. It's not being offered against  
3 McKesson, Your Honor.

4 MR. HESTER: Well, Your Honor, Your Honor, I would  
5 say once the document comes in for the truth, it's a  
6 document that would be relevant evidence against McKesson.  
7 So, it seems to me we're entitled to object.

8 THE COURT: Mr. Nicholas, you want to say  
9 something?

10 MR. NICHOLAS: Not really.

11 THE COURT: Well, you're supposed to stand up when  
12 you address the Court, too.

13 MR. NICHOLAS: I apologize, Your Honor.

14 THE COURT: Okay.

15 MS. MAINIGI: Your Honor, just for the purpose of  
16 the record, I also maintain our hearsay objection. Thank  
17 you.

18 THE COURT: All right. I'm not going to consider  
19 it for the hearsay, but I will admit it, for what it's  
20 worth, on the issue of the systemic failure, although --  
21 well, if we cut out all the hearsay of this, there's not  
22 much left, is there, Mr. Fuller?

23 MR. FULLER: Well, Judge, I've been told to cite  
24 the rules on my piece of paper.

25 THE COURT: Okay.

1                   MR. FULLER: So, under 801(d)(2)(A), a statement  
2 made by the party and in the individual purpose of their  
3 capacity, Cardinal signed the MOAs. So, they are admissions  
4 by Cardinal.

5                   And 801(d)(2)(B), statements of one of the parties  
6 manifested, or adopted, or believed to be true, they signed  
7 off on these MOAs, Your Honor.

8                   MS. MAINIGI: Your Honor, we disagree with that.  
9 We don't think that there are admissions and we think it's  
10 barred by 408.

11                  THE COURT: All right. I'm going to -- I'm going  
12 to admit it without -- and try to keep -- not consider the  
13 hearsay at this point.

14                  Go ahead, Mr. Fuller.

15                  MR. FULLER: Yes, Your Honor.

16                  BY MR. FULLER:

17                  **Q.** And, Mr. Mone, in 2012, the next action began with an  
18 administrative inspection warrant. Were you aware of that  
19 being served at the Cardinal Distribution Center?

20                  **A.** I was.

21                  **Q.** And were you involved in that process?

22                  **A.** I was not.

23                  MS. MAINIGI: Your Honor, I just want a continuing  
24 objection to this line of questioning.

25                  THE COURT: All right. The record will so show.

1 MR. FULLER: 44562.

2 BY MR. FULLER:

3 Q. I've passed you Plaintiffs' Exhibit 44562, Mr. Mone.

4 Do you recognize that document?

5 A. I do not.

6 MR. FULLER: Judge, I would, for non-hearsay  
7 purposes of notice and knowledge, I would move in 44562.

8 MS. MAINIGI: Your Honor, I object again on  
9 hearsay grounds, as well as geographic scope. I mean, you  
10 can look at the face of the document. A warrant is  
11 allegations. It proves absolutely nothing and you can see  
12 that this went to the Cardinal facility in Lakeland,  
13 Florida.

14 And I submit, Your Honor, that if we're going to --  
15 again, I did not object yesterday for some basic background  
16 information on these MOUs, but if they're going to present  
17 evidence of actions outside of Cabell and Huntington and  
18 spend significant amounts of their time doing that, I think  
19 we also have an unfairness issue because we didn't do  
20 discovery in this case related to those actions.

21 THE COURT: What's the purpose of this?

22 MR. FULLER: Judge, it again provides notice and  
23 knowledge. It's the basis of the MOU that you've just  
24 admitted into the record.

25 THE COURT: I think we're getting pretty far

1 afield here, Mr. Fuller. I'm going to sustain the objection  
2 to that.

3 MR. FULLER: Your Honor, one last one.

4 THE COURT: I'm encouraged by your referring to  
5 this as one last one.

6 BY MR. FULLER:

7 Q. Mr. Mone, do you recognize this document?

8 A. I do not.

9 Q. Were you aware that Cardinal entered into a Settlement  
10 Agreement with the DOJ and DEA in 2016 based on the 2012 MOU  
11 action?

12 MS. MAINIGI: Your Honor, this relates to --  
13 objection, I'm sorry. This relates to the same action that  
14 we were just talking about, the Lakeland. This is the  
15 Lakeland settlement.

16 THE COURT: What's the purpose of this, Mr.  
17 Fuller?

18 MR. FULLER: Your Honor, this is the Settlement  
19 Agreement that's related to the second MOU. If you turn to  
20 Page 3, Cardinal specifically signed off on and admits to  
21 violations of the Controlled Substance Act based on its  
22 system that was in place. I agree that these violations  
23 relate to the Lakeland Distribution Center, but it is a  
24 nationally operated system, particularly under Mr. Mone.

25 THE COURT: Well, I think this relates to the

1 issue of the systemic failure and I'm going to admit it, Ms.  
2 Mainigi.

3 MS. MAINIGI: Your Honor, thank you. I just want  
4 to respond to Mr. Fuller's allegation that the --

5 THE COURT: Okay.

6 MS. MAINIGI: Any admissions related to Lakeland.  
7 Thank you, Your Honor.

8 MR. FULLER:

9 Q. Mr. Mone, when you came in in December of 2007, you  
10 took on to review the system that was in existence, correct?

11 A. I did.

12 Q. And did you review how that system operated?

13 A. I did not review the specifics of how the system  
14 operated.

15 Q. And then you started building your own system, correct?

16 A. I did not. I continued the already established -- the  
17 already in-process changes that were being made to the  
18 system.

19 Q. I'm sorry. You did tell me that before. You mentioned  
20 that there was -- you mentioned that there was a Phase 1 in  
21 place, I believe?

22 A. I -- I don't believe I used the term Phase 1. There --  
23 the -- the system was migrating from the ILR system into the  
24 new electronic reporting system and it had already begun  
25 when I got there.

1       **Q.**   And you developed some -- you developed some portions  
2       of that new system, correct?

3       **A.**   I did.

4       **Q.**   Something known as Know Your Customer? Was that  
5       something that you implemented there at Cardinal?

6       **A.**   The Know Your Customer component of the SOM system was  
7       something that was developed and expanded during my time.

8       **Q.**   How about due diligence, is that something that you  
9       created there at Cardinal?

10      **A.**   I would not say that we created due diligence. We had  
11       always done due diligence. The manner by which we expanded  
12       the due diligence was done when I came into the role.

13      **Q.**   And that expansion had to do with centralizing the due  
14       diligence; is that correct, and electronically storing, I  
15       believe?

16      **A.**   I'm going to disagree with you because the electronic  
17       storage -- the due diligence piece is a different piece than  
18       the electronic component. When -- there are two different  
19       components of the SOM system.

20                    MR. FULLER: May I approach the witness, Your  
21       Honor?

22                    THE COURT: Yes.

23                    MR. FULLER: It's going to be 9734.

24                    BY MR. FULLER:

25       **Q.**   Mr. Mone, do you recognize this document?

1       **A.**    I do.

2       **Q.**    What is it?

3       **A.**    Well, the first page is an e-mail from me to Bob  
4 Giacalone on 6/30 of 2008 with the attachment being a  
5 PowerPoint, a series of slides on anti-diversion progress  
6 update.

7       **Q.**    And that PowerPoint presentation has a date of  
8 February 18th, 2008?

9       **A.**    It does.

10      **Q.**    Were you involved in the creation of that PowerPoint  
11 presentation?

12      **A.**    I was.

13      **Q.**    And did you forward it to Mr. Giacalone?

14      **A.**    I did.

15      **Q.**    Now, let me ask you, your first slide on Page 3 of that  
16 document, you talk about corporate investigations and key  
17 observations and recommendations, right?

18      **A.**    It -- if that is the title of the slide, yes.

19      **Q.**    And you make some comments related to the  
20 organizational structure, don't you?

21      **A.**    I do.

22      **Q.**    And these were based on your personal knowledge at the  
23 time, right?

24      **A.**    It was.

25      **Q.**    The investigation that you had done into the existing

1 system, correct?

2 **A.** I guess that's fair to say, the investigation that was  
3 done, yeah.

4 **Q.** And the finding that you made is inconsistent oversight  
5 of field QRA, right?

6 **A.** That is the statement that is made.

7 **Q.** And for the Court's benefit, field QRA is Quality  
8 Regulatory Affairs, correct?

9 **A.** That is correct.

10 **Q.** And did you -- Cardinal operated with compliance  
11 officers at the different distribution centers it had across  
12 the country; is that correct?

13 **A.** That is correct.

14 **Q.** Next, you find that inconsistent QRA participation and  
15 direction both in selection of personnel and training of  
16 personnel. So, some other of your concerns about the system  
17 that was being operated, correct?

18 **A.** I wouldn't call them concerns. They were  
19 identifications of areas for continuous improvement.

20 **Q.** Okay. And then skipping down a little bit, you find  
21 that there are communication gaps between QRA, Quality  
22 Regulatory Affairs, and the sales force, unclear decision  
23 rights, right?

24 **A.** That is stated on the form.

25 **Q.** You also noticed over the time there at Cardinal that

1       there was some contention or conflict between Sales and QRA  
2       at times, correct?

3       **A.**     I did not notice any conflict between Sales and QRA.

4       **Q.**     Never any issues between Sales and QRA in your mind?

5       **A.**     Not with regard to what we were doing.

6       **Q.**     Then in the resource section, the last bullet point  
7       that you have under resources is budgetary constraints and  
8       limited resources. That was another finding that you made,  
9       right?

10      **A.**     It was another observation.

11      **Q.**     And when you came to Cardinal and you met with Mr.  
12       Reardon, you had three staff members, didn't you?

13      **A.**     I did.

14      **Q.**     And that's excluding Mr. Reardon, correct?

15      **A.**     That is correct.

16      **Q.**     And it was Eric Brantley, Tim Dunham and Nick Rausch;  
17       is that right?

18      **A.**     That is correct.

19      **Q.**     Okay. And you felt that to properly operate the  
20       Anti-Diversion System at Cardinal you needed more help than  
21       just those three individuals, didn't you?

22      **A.**     I did.

23      **Q.**     If we turn the next page, Page 4 of the document, you  
24       talk about key action and people. Do you see that?

25      **A.**     I do.

1       **Q.**   And you added a Senior VP Supply Chain Integrity of  
2 Operations, right?

3       **A.**   That is correct.

4       **Q.**   You tried to add or added another VP, two directors and  
5 six investigators?

6       **A.**   That is correct.

7       **Q.**   I'm sorry.

8       **A.**   That's -- that's what's written on the slide.

9       **Q.**   Forming Anti-Diversion Team located in Dublin, Chicago,  
10 Lakeland, Swedesboro and Sacramento, right?

11      **A.**   That is correct on the slide.

12      **Q.**   Again, that's because your system was a national system  
13 operating everywhere, wasn't it?

14      **A.**   It was --

15                  MS. MAINIGI: Objection. Asked and answered, Your  
16 Honor.

17                  THE COURT: Overruled.

18                  THE WITNESS: It was a centralized system.

19                  BY MR. FULLER:

20      **Q.**   It says you aligned or added 24 field QRA Compliance  
21 Managers and that would be at the different distribution  
22 centers around the country, wasn't it?

23      **A.**   That is correct.

24      **Q.**   And prior to you making that addition or change, while  
25 the distribution centers may have had compliance officers,

1       they were given other duties and not necessarily full-time  
2       positions, right?

3       **A.**     That is correct.

4       **Q.**     And that's a change that you felt needed to happen to  
5       properly monitor anti-diversion?

6       **A.**     That is a change that I felt was necessary to meet our  
7       regulatory obligations.

8       **Q.**     And another change was the reporting requirement of  
9       those individuals. And I think that's in your next bullet  
10      point, realign regulatory operations and Anti-Diversion  
11      Reports of the Senior VP supply chain integrity, right?

12      **A.**     Yes.

13      **Q.**     And that would have been you, correct?

14      **A.**     Actually, no, it was not.

15      **Q.**     Who was the Senior Vice President?

16      **A.**     That would be Mark Hartman.

17      **Q.**     Your boss?

18      **A.**     My boss.

19      **Q.**     Fair enough. If you turn to Page 6 of the document,  
20      one of the goals that you were trying to accomplish and that  
21      you felt needed to be improved on was communication between  
22      Sales, Operations and QRA; is that right?

23      **A.**     I did.

24      **Q.**     And if we look down there, and we mentioned just a  
25      moment ago, when you came into the QRA Division they had

1       four people, Mr. Reardon, Mr. Brantley, Mr. Dunham and Mr.  
2       Rausch, correct?

3       **A.**     And the Distribution Compliance Officers.

4       **Q.**     Fair enough. While here you mark or indicate that  
5       you're going to try to re-educate the 40,000 domestic  
6       employees of Cardinal Health, correct?

7       **A.**     Yes.

8       **Q.**     If you'll turn to Page 10.

9                   MR. FULLER: Your Honor, at this time, I would  
10          move in Plaintiffs' Exhibit 9734.

11                  MS. MAINIGI: No objection, Your Honor.

12                  MR. FULLER: Could we pop that up?

13                  THE COURT: It's admitted.

14                   **PLAINTIFF EXHIBIT 9734 ADMITTED**

15                  MR. FULLER: Could we pop that up on the screen,  
16          please?

17                  BY MR. FULLER:

18       **Q.**     Mr. Hartman -- excuse me. Mr. Mone, this sets out the  
19       process -- well, for lack of a better term, Suspicious Order  
20       Monitoring System, right?

21       **A.**     It sets out a thought process of how to operate a  
22       system.

23                  MR. FULLER: And, Gina, if you could blow up the  
24       right side of the slide.

25                  BY MR. FULLER:

1 Q. And so, it starts with an order?

**A.**      Correct.

3 Q. Is that right?

4           **A.**      It does.

**A.** Generally electronically, yes, that is correct.

8 Q. And then that order goes into your -- during your time  
9 of your system, your automated system; is that correct?

10       **A.**     Into the electronic order monitoring system, yes, the  
11            electronic component.

12 Q. And you had built what is called thresholds and we'll  
13 talk more about those in a minute.

14 | A. Okay.

15 Q. Right?

**A.** That is correct.

17 Q. And a threshold, for the Court's benefit, is basically  
18 a number or a limit which a customer can order up to; is  
19 that fair?

20      | **A.**    No, it is not.

21 Q. What is a threshold?

22       **A.**     A threshold, I agree with you, is a number. It is not,  
23                  however, a limit.

24 Q. During the time of your system, was the threshold fixed  
25 so that a customer could not order above that number?

1       **A.**     A threshold was a fixed number that if an order came  
2                  through the system that was above that number, that order  
3                  would be held for evaluation.

4       **Q.**     And then you have two sections or two split-offs here.  
5                  You have a report, and I'm assuming that means report to the  
6                  DEA, correct?

7       **A.**     It does not.

8       **Q.**     Who would that be reported to then?

9       **A.**     That -- the system that you have here is the system  
10                 that we ultimately did not implement. It's the thought  
11                 process of a system that we initially thought about.

12      **Q.**     Okay.

13      **A.**     The reports are the threshold reports that are being  
14                 evaluated by the team.

15      **Q.**     And then the questionnaire, fax and/or call, is that  
16                 what we referred to earlier as sort of the due diligence  
17                 process?

18      **A.**     No. The due diligence process is beyond just this  
19                 piece, but it is the analysis that the team would conduct  
20                 with regard to an assessment of that held order.

21      **Q.**     Okay. And then that breaks off into either release or  
22                 report; is that right?

23      **A.**     That is correct.

24      **Q.**     And when we say release, that means release to whom?

25      **A.**     Release the order to the DEA registrant that ordered

1 it.

2 **Q.** And then the report is to report to the DEA?

3 **A.** That is correct.

4 **Q.** And then terminate means terminate the customer,  
5 correct?

6 **A.** That is a decision that may have been made with regard  
7 to a particular customer.

8 MR. FULLER: So, if we could bring up  
9 demonstrative or start with the animated version of 217.

10 MS. MAINIGI: Before you publish the  
11 demonstrative, Mr. Fuller, is -- if I could, is this your  
12 demonstrative?

13 MR. FULLER: I'm sorry. 2172.

14 MS. MAINIGI: Oh, 2172? Thank you.

15 BY MR. FULLER:

16 **Q.** All right. So, generally, in any sort of automated  
17 system, you have to have a triggering mechanism; is that  
18 right?

19 **A.** I would agree with that, yes.

20 **Q.** Now, Cardinal during your time used thresholds; is that  
21 fair?

22 **A.** Cardinal used thresholds as the initial inquiry into  
23 the evaluation, that is correct.

24 **Q.** And that's only one part of a Suspicious Order  
25 Monitoring System, correct?

1       **A.** Yes. There were other components.

2       **Q.** Okay. And the triggering system Cardinal used was to  
3 devise an average of the distributions nationwide, correct?

4       **A.** No, that is not correct.

5       **Q.** So, what is your understanding of how they devised the  
6 thresholds when you initially created the system?

7       **A.** To the best of my recollection, the manner by which we  
8 established those thresholds was to take a -- to take a  
9 dataset and to analyze that dataset based on unique  
10 characteristics of particular segmented customers.

11      **Q.** So, you divided the customers in different segments  
12 based on hospital, or pharmacies, or long-term care  
13 providers, whatever it may be, correct?

14      **A.** Correct.

15      **Q.** Okay. And then, did you subcategorize the customers by  
16 size?

17      **A.** We did.

18      **Q.** And then how did you determine size?

19      **A.** We determined size by characteristics such as total --  
20 total purchase price of controlled and non-controlled  
21 substances, by number of prescriptions, by a series of  
22 analyses based upon the questionnaires and knowing our  
23 customers' needs, the types of patients they were seeing,  
24 how close they were to hospitals, a number of factors.

25      **Q.** And so, once you determine what the customer's size is

1       in the different small, medium and large, I'm assuming,  
2       correct?

3       **A.**     We used those characteristics. We grouped them in that  
4       way, yes.

5       **Q.**     And then you would take an average for each of those  
6       categories, right?

7       **A.**     I believe that we took an average of those categories,  
8       yes.

9       **Q.**     And then you tripled the average, right?

10      **A.**     For some controlled substances, yes.

11      **Q.**     For oxycodone and hydrocodone, did you triple the  
12       averages?

13      **A.**     For -- for Schedule II controlled substances, we took a  
14       multiplier of three.

15      **Q.**     So, for each of the different categories, you then had  
16       an average -- and that was nationwide average, right?

17      **A.**     Well, no. It was a -- the statistics were designed on  
18       the manner by which we -- well, they were designed about how  
19       we segmented customers.

20      **Q.**     Sure. I'm sorry. Let me ask the question better.  
21       Based on segmentation and then size, then you took the  
22       average for that segment and that size of a customer for the  
23       entire nation?

24      **A.**     We applied it to all of the customers across the  
25       country.

1       **Q.**    Okay. And then you multiplied that number by three?

2       **A.**    The root number times three, yes.

3       **Q.**    Okay. So, that's your initial triggering system?

4       That's step one in your SOMS process, correct?

5       **A.**    The threshold is the triggering, yes.

6       **Q.**    So, Step 2, if you have a triggering event, you have to  
7       do something, right?

8       **A.**    Yes.

9       **Q.**    Yes, I'm sorry. It's next to you, too. I apologize.

10      **A.**    It's over here.

11      **Q.**    Does it matter --

12                  MS. MAINIGI: Excuse me, Mr. Fuller. May I -- I  
13       think this is a different demo. Which demo number is this?

14                  MR. FULLER: I'm sorry.

15                  MS. MAINIGI: You're going to go back to Demo 02?  
16       Thank you.

17                  MR. FULLER: Yes, ma'am.

18                  BY MR. FULLER:

19      **Q.**    All right. So, we have to do something if there's a  
20       triggering effect, correct?

21      **A.**    Yes.

22      **Q.**    And based on the way your system was designed, did it  
23       matter whether you were triggered just by a little bit or  
24       triggered by a lot?

25      **A.**    Once there was a trigger, there was an analysis.

1       **Q.**   So, let's -- for example, if we had a threshold that's  
2       10,000 pills of oxycodone and someone goes over it by a  
3       hundred pills, it still triggers in your system, correct?

4       **A.**   Yes.

5       **Q.**   And you would still have to take action, right?

6       **A.**   Correct.

7       **Q.**   Same example, but let's change the numbers. 10,000  
8       pill threshold, but they go over by 5,000 pills. It doesn't  
9       change at least this part of how the process works? You  
10      still have the triggering event and you still have to take  
11      action, correct?

12      **A.**   Yes.

13      **Q.**   Okay. Now, if you choose not to take action, can you  
14      cancel and report the order to the DEA?

15      **A.**   We -- I don't know what you mean by if you choose not  
16      to take action. We always took an action to do an  
17      evaluation.

18      **Q.**   Okay. So, your suggestion to the Court is that every  
19      order that triggers is going to have some sort of due  
20      diligence?

21      **A.**   Yes.

22      **Q.**   And that due diligence is going to be documented,  
23      correct?

24      **A.**   That due diligence would be documented in the system.

25      **Q.**   And when we're doing the due diligence, what we're

1       trying to do is to determine whether we can clear this order  
2       or whether we have to report the order to the DEA, correct?

3       **A.**     Yes.

4       **Q.**     So, let's go to Step 3. So, Step 3, if we have  
5       adequate due diligence that clears the order, whatever  
6       amount it is, it's your understanding that under your system  
7       you would then be cleared to ship the order?

8       **A.**     Yes.

9       **Q.**     If you conduct the due diligence and you cannot clear  
10      it, meaning you cannot validate the order, it's not likely  
11      to be diverted, then you have to -- you have a suspicious  
12      order that's not cleared and you have to block it and report  
13      it, correct?

14      **A.**     Yes.

15      **Q.**     Okay. Do you know how many suspicious orders you  
16      reported into Cabell or Huntington?

17      **A.**     I do not.

18      **Q.**     Do you know how many suspicious orders you reported  
19      into the State of West Virginia during your time? And I  
20      want to limit the questions. Let me go back for a second.

21                  During your tenure, what we described as Chapter 2,  
22                  from the end of -- December of '07 to September of '08 -- or  
23                  to September of '12, do you know how many suspicious orders  
24                  you reported into Huntington and Cabell County?

25      **A.**     I do not.

1 Q. Do you know how many suspicious orders you reported to  
2 the State of West Virginia?

3      | A. I do not.

4 Q. Now, your system, this electronic system, you had  
5 access to threshold and threshold breaches, correct?

6           **A.**     I did, yes.

7 Q. And would you review thresholds and threshold breaches?

8      **A.**     Not ordinarily.

9 Q. But did you have access to the system?

10      **A.**    As I said before, I did have access to them.

11 Q. Could you have reviewed them?

**A.** I could have, yes.

13 Q. And if you were looking at a particular pharmacy, is  
14 that something that you might do?

15           **A.**     I might, yes.

16 Q. And when we say thresholds, thresholds may change over  
17 time. It didn't stick to the three time multiplier,  
18 correct?

**A.** That is correct.

20 Q. And if we're going to change a threshold, we have to go  
21 through certain steps to do that, don't we?

22       **A.**     The team would do an evaluation and to whether or not  
23                  to make a change in a threshold.

24 Q. And there are certain justified reasons for changing a  
25 threshold correct?

1       **A.**     There would be.

2       **Q.**     And there are certain reasons we wouldn't want to  
3            change a threshold, correct?

4       **A.**     There would be.

5       **Q.**     And those reasons need to be documented in that  
6            customer's due diligence file, correct?

7       **A.**     The rationale would have to be up to the pharmacist. I  
8            don't recall a specific requirement, and I could be  
9            incorrect, but I don't recall a specific requirement that  
10          the reasons themselves be documented. All of -- well, when  
11          I say reasons, I mean the totality of all the reasons.

12       **Q.**     But there has to be some basis documented, correct?

13       **A.**     There's going to be a basis for the pharmacist, member  
14          of the team, to make a decision.

15       **Q.**     And when you say pharmacist, so the Court is clear,  
16          we're not talking about the pharmacists at the pharmacy.  
17          We're talking about the pharmacist at Cardinal that's job is  
18          to evaluate thresholds and whether one needs to be changed?

19       **A.**     Our team of pharmacists and staff on the QRA Team, yes,  
20          Your Honor, not the pharmacy piece, just our little piece of  
21          the pie.

22       **Q.**     And if we are going to make a choice based on a trigger  
23          and clear an order to be shipped, the basis of that  
24          clearance needs to be documented, as well, correct?

25       **A.**     Like I said, I don't recall that. The base -- all of

1       the reasons why a pharmacist made a -- pharmacist/pharmacist  
2       team made a decision, but there had to be a rational basis  
3       for doing so.

4       **Q.**     And we need to be able to know what that rational basis  
5       is; is that fair?

6       **A.**     The -- because those pharmacists were continually  
7       working in the same area, they had to be satisfied with the  
8       decisions that they made and they would record what they  
9       felt was necessary to refresh their recollection, I would  
10      assume, as to why they made a prior decision to go up or to  
11      go down.

12                  MR. FULLER: Judge, it's right at 10:30. I'm  
13      going to switch topics.

14                  THE COURT: Good time for a break, Mr. Fuller.  
15      We'll be in recess for ten minutes.

16                  (Recess taken)

17                  (Proceedings resumed at 10:42 a.m.)

18                  THE COURT: Mr. Mone, you can resume the  
19      witness stand, sir.

20                  THE WITNESS: It's a lot longer walk than you  
21      think it is.

22      BY MR. FULLER:

23       **Q.**     Mr. Mone, we're talking about the implementation of  
24       your system. And at the time, there's several  
25       distribution centers that have their license suspended;

1           correct?

2       **A.**    Yes, they were.

3       **Q.**    At that, that point in time -- at that point in time,  
4           there was an issue with compliance of Valencia distribution  
5           center; is that right?

6       **A.**    Not at that time.

7       **Q.**    Was it shortly thereafter?

8       **A.**    The concern associated with Valencia was a concern  
9           expressed by the Drug Enforcement Administration after --  
10          way after the, the period of time of the Immediate  
11          Suspension Orders.

12       **Q.**    When you say way after, would it have been early '09?

13       **A.**    I believe it was sometime in the spring of '09, that's  
14          correct.

15       **Q.**    And were there meetings with DEA related to that issue?

16       **A.**    There were.

17       **Q.**    Did Cardinal -- based on the meetings with DEA, did  
18          Cardinal make certain additional changes to its system to  
19          continuously improve that system?

20       **A.**    I do not recall whether we made changes to our system  
21          as a result of the Valencia concern. We were always engaged  
22          in taking the available information and continuously making  
23          improvements to the system. So I don't know that I can say  
24          point to serial that they were directly related.

25       **Q.**    During that same time frame, and I mean early 2008,

1       were you aware of Dendrite being hired to do an evaluation  
2       of the system, Mr. Ron Buzzeo?

3       **A.**      The, the work that Ron Buzzeo's group did with my team  
4       was that they provided additional resources for  
5       investigations.

6       **Q.**      Do you remember being interviewed by Mr. Buzzeo related  
7       to the functioning of that system?

8       **A.**      I don't remember -- I don't remember an interview by  
9       Ron. I know that Ron and I had talked, but I don't have any  
10      specific recollection of an interview.

11                  MR. FULLER: May I approach, Judge?

12                  THE COURT: Yes.

13                  BY MR. FULLER:

14       **Q.**      Mr. Mone, do you recognize this document?

15       **A.**      I do not.

16                  MS. MAINIGI: Your Honor, I have an objection to  
17       the use of this document which is P-45. There are multiple  
18       objections.

19                  I think the witness has indicated he doesn't recognize  
20       the document. The document is hearsay. And there was a  
21       privilege objection in the MDL court related to this  
22       document. That privilege objection was ultimately overruled  
23       by Special Master Cohen.

24                  But just for the purpose of the record, we continue to  
25       assert our privilege objection to this -- for the purpose of

1           the record here. But foundationally I don't think that they  
2 can cover this document with this witness.

3           THE COURT: Well, he said he didn't recognize it.

4           Go ahead, Mr. Fuller.

5           MR. FULLER: Thank you, Judge.

6           BY MR. FULLER:

7           Q. Mr. Mone, if you'll turn to the second page of this  
8 document --

9           MS. MAINIGI: Objection, foundation.

10          THE COURT: Well, yeah. How -- just address her  
11 objection and --

12          MR. FULLER: Sure, Your Honor. Quite frankly,  
13 I'll just move it into evidence, Your Honor. This is one of  
14 the stipulated documents. I don't necessarily need to ask  
15 the witness about it. He's referenced in it and there's  
16 emails from him attached to it.

17          THE COURT: Can I admit it as one of the  
18 stipulated documents if he's not questioned about it?

19          MR. FULLER: We would submit it only for notice  
20 and knowledge, Judge.

21          MS. MAINIGI: Your Honor, we have stipulated to  
22 authenticity and no sponsoring witness, but we still have a  
23 hearsay objection related to it, as well as lack of  
24 knowledge and the previously stated 403. But we maintain a  
25 hearsay objection in addition to the others.

1                   THE COURT: Well, he's saying he's not admitting  
2 it for the hearsay, only to knowledge and notice. Can I  
3 admit it for that limited purpose?

4                   MS. MAINIGI: I don't think so, Your Honor,  
5 because this particular witness did not get this document.  
6 So if he's the head of the Anti-Diversion and he did not get  
7 this document, I don't know what kind of notice it serves  
8 as, and it is otherwise hearsay.

9                   THE COURT: Okay. I'll sustain the objection for  
10 now. Maybe you can get it in some other way.

11 BY MR. FULLER:

12 Q. All right. 9809. Mr. Mone, do you recognize this  
13 document which is Plaintiffs' 9809?

14 A. I do not.

15 MR. FULLER: Judge, I would move this one in for  
16 the record. This is, again, another stipulated document.  
17 It's by Cardinal's counsel to DOJ and it revolves around the  
18 Valencia distribution center and promises made by Cardinal.

19 MS. MAINIGI: Your Honor, I object. I disagree  
20 that this is a stipulated document. I do not believe it is.  
21 Perhaps I'm wrong and Mr. Fuller can show me that. But our  
22 records do not indicate this is a stipulated document.

23 We've already established there's no personal knowledge  
24 related to this document. And, more significant than that,  
25 Your Honor, is that it's completely irrelevant to

1 Cabell/Huntington.

2 The Valencia distribution center is in California.

3 This document is a letter from outside counsel for Cardinal  
4 to the DEA related to this facility in Valencia, California.

5 It has nothing to do with anything here, Your Honor.

6 THE COURT: I'll sustain the objection, Mr.  
7 Fuller.

8 MR. FULLER: Yes, Your Honor.

9 BY MR. FULLER:

10 Q. 14122. Mr. Mone, do you recognize this document?

11 A. The first page of the document is an email from Tony  
12 Romano on 5/6 of 2008.

13 MS. MAINIGI: Mr. Fuller, could I get a copy of  
14 the document, please?

15 THE WITNESS: It reflects -- it's a series of  
16 PowerPoint slides.

17 BY MR. FULLER:

18 Q. And who is Mr. Romano? Do you know?

19 A. Mr. Romano -- I don't recall what his title was, but he  
20 worked in the sales operations area. And I'd like to think  
21 that he was the, the training expert.

22 Q. Well, it says "Director of Sales Training" there on his  
23 signature line; right?

24 A. It would help -- I apologize. I didn't read the whole  
25 document.

1       **Q.**    This was sent on or about May 6th of 2008; is that  
2 right?

3       **A.**    That is correct.

4       **Q.**    And he's providing you with these PowerPoints as well  
5 as, apparently, two video presentations that were given as  
6 part of the training at Cardinal; correct?

7       **A.**    Correct.

8       **Q.**    And that was something that you would be somewhat  
9 involved in, particularly as to the training related to QRA;  
10 is that right?

11      **A.**    Yes, that is correct.

12      **Q.**    And you've seen some of these slides in the past;  
13 correct?

14      **A.**    I have.

15                    MR. FULLER: Your Honor, at this point I would  
16 move in Plaintiffs' 14122 into evidence.

17                    THE COURT: Any objection to 14122?

18                    MS. MAINIGI: No, Your Honor.

19                    THE COURT: It's admitted.

20 BY MR. FULLER:

21      **Q.**    Now we have it up on the screen.

22      **A.**    Okay.

23      **Q.**    And this packet includes several different  
24 presentations; is that correct?

25      **A.**    It, it does.

1       **Q.**     If you could turn to Page 3 of the document. It's  
2 talking about the kick-off. Do you see George Barrett  
3 there? Who's George Barrett? Do you know?

4       **A.**     At the time, George Barrett was the vice chairman of  
5 the supply chain division of Cardinal Health as well as the  
6 CEO.

7       **Q.**     And Jeff Henderson, do you know who he is?

8       **A.**     He was the chief financial officer of the organization.

9       **Q.**     And Mark Hartman, he's your boss; is that correct?

10      **A.**     That is correct.

11      **Q.**     Turn to -- go back to Page 8. Actually -- I'm sorry.  
12      Let's go to Page 10.

13      **A.**     Page 10?

14      **Q.**     Yes.

15      **A.**     Yes, sir.

16      **Q.**     All right. Can you blow that up. Thank you.  
17      It's talking about DEA guidance. Do you see that?

18      **A.**     That is the title of the slide.

19      **Q.**     And are you aware of what Cardinal needs to do to  
20      ensure compliance with both the Controlled Substances Act as  
21      well as implementing regulations?

22      **A.**     I have a general knowledge of what was expected, yes.

23      **Q.**     And is that sort of a two-step process, meaning that  
24      you have to maintain effective controls to prevent  
25      diversion?

1       **A.**     The, the statutory requirement of the Controlled  
2              Substances Act says to maintain effective controls against  
3              diversion.

4       **Q.**     Okay. And then there's a separate reporting  
5              requirement, isn't there?

6       **A.**     There is a reporting requirement.

7       **Q.**     And that required you to report suspicious orders when  
8              discovered. Those would be orders of unusual size, pattern,  
9              and frequency. Correct?

10      **A.**     They would be orders of unusual size, orders deviating  
11              substantially from a normal pattern, and orders of unusual  
12              frequency.

13      **Q.**     In your triggering system, the way it was designed only  
14              measured orders of unusual size; correct?

15      **A.**     It did not.

16      **Q.**     Okay. So let me ask it differently. Your threshold  
17              system only measured orders of unusual size; correct?

18      **A.**     No, it did not.

19      **Q.**     How did -- explain to the Court how your threshold  
20              system monitored orders of unusual pattern or frequency.

21      **A.**     The threshold system, while it used a reference number  
22              of the threshold, we produced additional reports below the  
23              threshold number that the pharmacist would analyze, and  
24              reports that would look at pattern and frequency, as well as  
25              the fact that the threshold system itself in looking at that

1       order that broke a particular size, that -- in the analysis  
2       you could look at all of the orders below that to assess a  
3       pattern, assess a frequency.

4           And in doing so on a 30-day rotational basis, you were  
5       able as a pharmacist, member of the team, to analyze all of  
6       the additional characteristics; its size, unusual size,  
7       deviating substantially from a normal pattern, and unusual  
8       frequency.

9           So the system itself is a very broad, comprehensive  
10      system.

11       **Q.**    And let me back up and maybe my question was a little  
12      unfair, so let's go back.

13           As to the triggering mechanism, being the threshold,  
14      that's based on volume in and of itself; correct?

15       **A.**    The threshold -- the threshold is based upon the -- the  
16      threshold is based upon a number, a size.

17       **Q.**    Okay. So my question pertains just to the threshold  
18      and the triggering event. That only measures volume; right?

19       **A.**    The threshold itself in the way it's constructed  
20      assesses a volume analysis. But inside that volume  
21      analysis, because you are looking at specific orders for  
22      specific -- specific orders for specific customers, you are  
23      able to do in that analysis the deviating from an unusual  
24      frequency, unusual frequency, and the rest of --

25           THE COURT: I'm going to have to interrupt you.

1 I've got a technological breakdown here.

2 (Pause)

3 It's working. Yeah, that's fine.

4 BY MR. FULLER:

5 **Q.** So that additional analysis is what your pharmacist  
6 would do; correct?

7 **A.** The pharmacist team, yes, that is correct.

8 **Q.** And here if we go back to the PowerPoint, it says,  
9 "Reporting suspicious orders to the DEA does not relieve the  
10 distributor of the responsibility to maintain effective  
11 controls to prevent diversion."

12 And you agree with that; correct?

13 **A.** First of all, this is not my slide. I believe if you  
14 are looking to the correspondence that that statement does  
15 appear in DEA correspondences.

16 **Q.** My question is, as the one running the Anti-Diversion  
17 Control Program at Cardinal for the Chapter 2 time frame, do  
18 you agree with that statement?

19 **A.** Yes. The reporting of suspicious orders is not the  
20 totality of the obligation.

21 **Q.** And a registrant, such as Cardinal, has an obligation  
22 beyond just reporting suspicious orders; correct?

23 **A.** It does. The, the obligation is to maintain effective  
24 controls against diversion. And amongst, amongst others,  
25 you've got the security requirements that are associated

1       with the distribution centers. So, yeah, there are things  
2       beyond just that one particular regulation.

3       **Q.**     So do you agree that shipping suspicious orders is not  
4       maintaining effective controls against diversion?

5       **A.**     I would not agree. The, the obligation is to report  
6       suspicious orders. The, the regulation says develop a  
7       system, implement that system to report suspicious orders of  
8       controlled substances. That's the obligation.

9       **Q.**     But you also have an obligation to maintain effective  
10      controls to prevent diversion; right?

11      **A.**     In, in the CSA there is that requirement to maintain  
12      effective controls against diversion.

13      **Q.**     And, and according to Mr. Mone, effective controls  
14      still means we can still ship out onto the streets, into  
15      pharmacies suspicious orders?

16      **A.**     No, it does not.

17      **Q.**     So we must not ship suspicious orders to prevent  
18      diversion?

19      **A.**     Suspicious -- once a suspicious order is identified,  
20      that suspicious order is reported, is reported to DEA and  
21      not shipped to the customer.

22      **Q.**     And, so, do you -- I'm a little confused now because  
23      what I'm trying to figure out, since it's obviously an issue  
24      in the case, is whether maintaining effective controls  
25      requires us to not ship suspicious orders.

1           If we're going to maintain effective controls to  
2 prevent diversion, how can we ship an order that's  
3 determined to be suspicious?

4           MS. MAINIGI: Objection, Your Honor. I think this  
5 has been asked and answered and I'd also like a  
6 specification as to the time frame.

7           THE COURT: It's certainly been asked and  
8 answered. So I'll sustain the objection.

9           BY MR. FULLER:

10          **Q.** Mr. Mone, let's turn to Page 17. Did you utilize  
11 the sales force to assist with your Anti-Diversion  
12 system?

13          **A.** The sales force was a component of the SOM system.  
14 They did participate.

15          **Q.** And here it mentions that they're the boots on the  
16 ground and the front line defense. Do you agree with that?

17          **A.** I believe that the sales force were the first line of  
18 the front line -- I wouldn't necessarily call it the front  
19 line of defense. My analysis on it is they're the front  
20 line of visibility for the company.

21          **Q.** And they have the most, probably, interactive contact  
22 with the customer; is that right?

23          **A.** They do.

24          **Q.** We'll keep working our way through this. Let's go back  
25 to Page 86.

1           During this time when you arrived at Cardinal's  
2 headquarters in November -- excuse me -- December of 2007,  
3 do you believe that this country was facing an opioid  
4 epidemic?

5       **A.**   I believe that since the first person chewed on a leaf  
6 and found a berry that they liked and it caused a reaction  
7 in the brain that society has had a substance use disorder.

8           I -- I'm not -- I can't tell you whether it's an  
9 epidemic or not. I'm not an epidemiologist. But I can tell  
10 you with certainty that we have a public health crisis with  
11 the use of medicines.

12      **Q.**   And was that -- did we have a public health crisis  
13 related to the use of medicines related to opioids back in  
14 2006 and 2007?

15      **A.**   We did.

16      **Q.**   Do you know if we have that public health crisis in  
17 Cabell County?

18      **A.**   I have no specific knowledge about the county's public  
19 health crisis. But what I can tell you is systemically  
20 across the United States --

21      **Q.**   It's everywhere?

22      **A.**   -- we have an issue with regard to the substance use  
23 disorder that originates with the prescribing of controlled  
24 substances. And, and, of course, obviously, controlled  
25 substances includes opioids.

1       **Q.**    So let's keep going. Let's turn to Page 100.

2                  Here we're going to talk a little bit about your  
3 on-boarding process. Is there a process that you go through  
4 under your system at Cardinal when you're bringing on a new  
5 pharmacy?

6       **A.**    We did have a process to, to bring on a, a new  
7 customer.

8       **Q.**    And that process requires a site visit; correct?

9       **A.**    It did.

10      **Q.**    That process also required a new customer  
11 questionnaire; is that correct?

12      **A.**    It did.

13      **Q.**    That's a questionnaire that you had devised and  
14 implemented at Cardinal; correct?

15      **A.**    We -- the team, you know, it was a team effort. It's  
16 not one person. It was a team effort to develop the  
17 questionnaire to ascertain facts that we felt were relevant.

18      **Q.**    Your department?

19      **A.**    Oh, yeah.

20      **Q.**    You also came up with other information that you had  
21 gathered related to these new customers; correct?

22      **A.**    Yes, we would gather additional information.

23      **Q.**    What would that include?

24      **A.**    Well, to the extent, you know -- obviously, the first  
25 two requirements is to recognize that the entity had a state

1 license and, where required, a state controlled substance  
2 license and a DEA registration.

3 And we would have folks collect demographic data,  
4 information such as how close they were to a hospital,  
5 information about the types of patients, you know, whether  
6 they had, whether they took care of senior citizen centers,  
7 you know, trying to get -- again, the questionnaire was  
8 about know your customer, know the characteristics of the  
9 customer to be able to understand their business needs.

10 **Q.** Would you tend to validate the information provided by  
11 the customer?

12 **A.** Where the information was subject to objective  
13 validation like, like the DEA license and the Board of  
14 Pharmacy license, yes, we would, we would attempt to do so  
15 where we could obtain objective information.

16 **Q.** It also lists here on the PowerPoint existing stores  
17 that have a 12-month total dollar purchase from prior  
18 wholesaler and if computer can provide a breakdown of the  
19 monthly purchases of controlled substances. That's  
20 important. Correct?

21 **A.** Yes. If they were transitioning from a different  
22 wholesaler to us, so they were -- you know, a new store to  
23 us, we would look at in terms of understanding and look for  
24 the consistency between the representations they made on the  
25 customer questionnaire to the data that they provided.

1       **Q.**   And all this is part of being vigilant as a  
2 distributor, as a registrant to ensure we're not  
3 over-supplying somebody; correct?

4       **A.**   It is all part of the due diligence process to make a  
5 decision as to whether or not an individual customer would  
6 become a Cardinal Health customer.

7       **Q.**   Now, could a customer refuse to provide some of this  
8 information?

9       **A.**   If a customer -- could they? Yeah, a customer could  
10 refuse to provide some of that information. Then we would  
11 take that under consideration as to whether or not to open  
12 them up or not.

13      **Q.**   Meaning that might be a red flag; right?

14      **A.**   We would consider that a, a -- we would consider it  
15 amongst the totality of the circumstances as to whether or  
16 not we would open a customer and allow them to purchase  
17 medicines from us.

18      **Q.**   And what about top prescribers? Would you obtain that  
19 information from them?

20      **A.**   Initially because -- in the initial stages of where we  
21 were in the development of the program and because much of  
22 the, much of -- not the totality of, but much of the  
23 emphasis was on internet pharmacies, the top prescribers  
24 were an element of analysis.

25      **Q.**   And then a determination is made as to whether to sign

1       on that customer?

2       **A.**     That is correct.

3       **Q.**     And who determines what the threshold is going to be  
4           initially for the customer?

5       **A.**     It was -- the initial thresholds were determined based  
6           upon an analysis by the analytics team and the pharmacist  
7           team after they have made a determination that the  
8           information on the customer was sufficient to open up a  
9           customer.

10      **Q.**     Now, let's still deal with new customers, but let's  
11       switch over to chains. Did chains go through a different  
12       process in on-boarding?

13      **A.**     Chains did go through a different process in  
14       on-boarding.

15      **Q.**     And was that controlled by your department or some  
16       other department?

17      **A.**     It was still controlled by our department.

18      **Q.**     And who had control of whether a chain was on-boarded?

19      **A.**     Still our -- still our team had a -- had the decision  
20       as to whether or not a new chain would be added to, as a  
21       customer.

22      **Q.**     And this important information that we've been talking  
23       about, would you get the same information from the chain  
24       customer?

25      **A.**     Sometimes we did, sometimes we did not.

1           **Q.**    Why would there be occasions where you would not?

2           **A.**    The occasions where we would not were situations where  
3           the, the, the, the data either was not available because it  
4           was a, it was a brand new store, there was nothing there,  
5           you know, they put a new building in, and sometimes we would  
6           use the analysis of the characteristics of the chain in  
7           terms of whether it's a 24-hour store, where it was located  
8           to place them in the segmented categories that we may have  
9           had for that particular chain.

10          **Q.**    Were there certain chains that wouldn't provide you  
11          information when requested; for example, CVS?

12          **A.**    To the best of my recollection, whenever we requested  
13          information, we received the information from the chain in  
14          order to enable the, the, the pharmacist team to make a  
15          decision.

16          **Q.**    And then on top of that, I think you stated in the past  
17          that you would determine what their SOMS system was; is that  
18          correct?

19          **A.**    We would determine based upon the factors that we knew  
20          about, the new location, where they fit in terms of  
21          characteristics, recognizing that the, the chain itself had  
22          some fairly unique, you know, standard characteristics;  
23          24-hour stores, you know, where they were located, et  
24          cetera, put those into the segmentation. And we would  
25          segment them and start their initial thresholds at that

1       segmented area, you know, whatever we -- wherever we  
2       categorized them, you know.

3       **Q.**     My question was a little different than that. Do you  
4       know what type of SOMS system that the chains had?

5       **A.**     Oh, that the chains themselves have?

6       **Q.**     Yes.

7       **A.**     I do not know what -- I do not know the specifics of  
8       the systems that the chains themselves used.

9       **Q.**     So were you during this time frame relying on the  
10      chains to conduct their own due diligence?

11      **A.**     No, we were not relying on the chains to do their own  
12      due diligence. We were in a collaborative and cooperative  
13      relationship with the chains to communicate information back  
14      and forth. We didn't rely on them. We did our own analysis  
15      based upon what we would discern.

16      **Q.**     Now let's go to Page 114.

17      **A.**     Yes.

18      **Q.**     Here we're dealing with thresholds; right?

19      **A.**     Yes, sir.

20      **Q.**     And under your time frame, thresholds were  
21      non-disclosable to sales as well as to customers; is that  
22      right?

23      **A.**     This is correct.

24      **Q.**     And that's because you believed that it would be -- or  
25      raise the eye of someone if you were telling them what their

1 thresholds were; correct?

2       **A.** My belief in not disclosing the threshold was that I  
3 didn't want customers to know specifically what their  
4 threshold was in case they wanted to attempt to manipulate  
5 the threshold system, recognizing that once they had a DEA  
6 registration, they could purchase from any wholesaler.

7       **Q.** And a lot of pharmacies had a secondary purchaser as  
8 relates to a distributor; correct?

9       **A.** I, I believe that it's probably fair to say that every  
10 pharmacy had at least a secondary wholesaler.

11      **Q.** And if someone knew what their threshold was, they  
12 could order up to a threshold and then turn around and go to  
13 their secondary for the same drug class or drug family to  
14 order additional product; correct?

15      **A.** And that was the reason why we initially decided not to  
16 disclose the threshold.

17      **Q.** And, and let's walk through a little more on these  
18 thresholds in detail.

19           So the Court understands, each drug family or base code  
20 has its own individual threshold; is that correct?

21      **A.** That is correct, in the system that we implemented.

22      **Q.** Of particular relevance to us in this case is that  
23 oxycodone and hydrocodone would each have their own  
24 independent threshold. Is that true?

25      **A.** That is correct.

1       **Q.** Now, at some point, you guys began to use sub base  
2 thresholds; correct?

3       **A.** Yes, we did.

4       **Q.** And --

5       **A.** I don't recall when that occurred.

6       **Q.** And that was a system where we looked at the more  
7 abused substances and set a separate threshold for those;  
8 for example, maybe oxy 30. Correct?

9       **A.** The, the sub segmentation of a particular family was  
10 designed to gather information about the, the prescribing  
11 because it all starts with prescribing, the prescribing and  
12 dispensing at that particular location. It gives a better  
13 analysis than just a single number which is, in fact,  
14 continuous quality improvement.

15      **Q.** And another reason we don't disclose the threshold is  
16 because we want to capture the intent of the customer; is  
17 that right?

18      **A.** That, that's the analysis that I used in terms of  
19 capturing intent.

20      **Q.** Explain to the Court what we mean by capture the  
21 intent.

22      **A.** Well, I wanted to capture -- I didn't want the  
23 customer -- first of all, I didn't want the customer to  
24 manipulate the system by knowing the threshold and doing  
25 other things. But capturing their intent was to see that

1       they would hit the threshold and then move to a secondary  
2       supplier.

3           Why I wanted that particular information, recognizing,  
4       of course, that the first time we hit the threshold, they  
5       could just figure out what the threshold was. I wanted it  
6       to be able to set-off for our team that initial inquiry into  
7       that particular customer.

8           So I captured their intent, their growth, what was  
9       happening with the customer so that we could make  
10      appropriate investigation of what was happening with the  
11      customer.

12     **Q.**    Let's go next to Page 120.

13           All right, QRA evaluation. Now, at this point in the  
14      process, we went from having a threshold. Now this is the  
15      discussion related to evaluating that threshold event.  
16      Correct?

17     **A.**    Yes, sir.

18     **Q.**    All right. And then it says here that one of the  
19      things that you're going to do is you're going to review  
20      12-month historical purchases; is that right?

21     **A.**    Yes, sir.

22     **Q.**    And that means the sales of that customer -- sales of  
23      Cardinal to that particular pharmacy?

24     **A.**    That is correct, assuming, of course, we had 12 months  
25      of data.

1       **Q.**    Sure. Assuming they have been a customer for 12  
2 months?

3       **A.**    Right.

4       **Q.**    Now, you could also obtain what's called -- I think  
5 it's called a Drug Utilization Report from the pharmacy  
6 itself; correct?

7       **A.**    We would, we would often -- the pharmacist would often  
8 request the Utilization, yes.

9       **Q.**    When you say "the pharmacist," again we're talking  
10 about Cardinal's pharmacist?

11      **A.**    Yes.

12      **Q.**    And explain to the Court what a Drug Utilization Report  
13 is from one of your customers.

14      **A.**    So a Drug Utilization Report is a, is a  
15 computer-generated summary of -- without patient data, so  
16 there's no -- because of HIPAA laws, there's no patient  
17 data. It's a summary description of the drug and, depending  
18 upon the system, you know, the number of prescriptions, the  
19 quantity of those, the quantity dispensed for that  
20 particular drug family.

21           So a Drug Use Report would be the dispensing  
22 information that was, was performed by the pharmacy pursuant  
23 to prescriptions presented to it.

24      **Q.**    So, basically, from the Drug Utilization Report you  
25 could see what that pharmacy is dispensing; correct?

1       **A.**    We could see the total quantity of the drugs.  
2       Depending upon the, the nature of the report, yes, we should  
3       be able to see in the Drug History Report the total quantity  
4       dispensed.

5       **Q.**    That would also give rise to determining whether  
6       they're ordering from someone else; correct?

7       **A.**    You could infer that, you know. Because the delta  
8       between those two numbers may, in fact, depending upon the  
9       number, be the, the drug quantity that's on the shelf at the  
10      pharmacy. So it requires a little bit of analysis, but  
11      you're teasing out information as best you can.

12       **Q.**    The second point here is the questionnaire sent by  
13      sales operations to customers to inquire about the order.  
14      "Why" basically? Correct?

15       **A.**    The "why." Why did you need this? What's going on?  
16      What's changed?

17       **Q.**    And that questionnaire -- during your time, was it  
18      electronically completed?

19       **A.**    It varied, you know. At the beginning of the system,  
20      we were paper-based. At the beginning of the system, we  
21      were paper-based and fax-based and what have you. As we  
22      designed and continued to improve the system, it became  
23      electronic.

24       **Q.**    Now, just so we're clear, you said the beginning of the  
25      system. You're talking about when you arrived in 2007,

1           2008?

2       **A.**    Oh, yeah. At the beginning -- at the beginning of the  
3           implementation of the changes to migrate to this type of  
4           system, we were paper-based.

5       **Q.**    Next Power -- next point says "Questionnaire sent to  
6           QRA by customer, the plausibility evaluation."

7       **A.**    Yes.

8       **Q.**    Is that where you're evaluating the basis of their  
9           explanation?

10      **A.**    That is where the pharmacist team would take the  
11           information based upon their knowledge and experience, the  
12           pharmacist and analytics, to look at the data that was  
13           coming back and to make a decision what to do with that  
14           order.

15      **Q.**    And this is verified by a site visit?

16      **A.**    There, there were opportunities whereby the pharmacist  
17           team, in their evaluation, would say this is plausible,  
18           plausibility evaluation. If the order is not suspicious,  
19           let's go look at the pharmacy to see the rest of the story,  
20           the totality of the story, you know. And we would set up  
21           our investigatory team to go do a site visit.

22      **Q.**    And this is all a process that has to be gone through  
23           when we have a triggering event to clear an order; correct?

24      **A.**    Not necessarily. This process -- the, the verification  
25           by a site visit was not an absolute default. As I said

1       earlier in the last response, the pharmacist may determine  
2       that the order was okay, the plausibility piece. But in, in  
3       their professional decision, they wanted a site visit.

4           And, so, they would set up a site visit with the  
5       investigatory team. It didn't change the nature of their  
6       assessment of the order. It just said let's go to the  
7       customer for the rest of the story.

8       **Q.** This process that's gone through, we would see some of  
9       that documented in the due diligence file for that  
10      particular customer; correct?

11       **A.** In the early stages of the system, those -- the  
12      documentation would be on paper in a file. Later on, that  
13      information was retained in an electronic system.

14           The documentation was not the totality of the -- what  
15      was going on in the heads of the professionals that we were  
16      using. It may simply have been a summary analysis, a  
17      shorthand version of, say, yes, I've done my diligence and  
18      I've done the totality of the circumstances review and I've  
19      made a decision.

20       **Q.** But we're going to have the questionnaire -- we're  
21      going to have the response to the questionnaire. Any of  
22      that additional information is going to be compiled in that;  
23      correct?

24       **A.** Some of that information -- you know, the questionnaire  
25      more than likely would be there. Some of that information

1 would be retained.

2         However, depending upon the time frame and the  
3 circumstances, not every document is going to be in  
4 existence today 12 years later -- well, 11, however many  
5 years later we are -- on a paper system. Some of those  
6 paper systems were -- the records retention policy was two  
7 years and some of those paper documents don't exist any  
8 more.

9         Q. Let's go to Page 122.

10                 THE COURT: Let me ask you a question that just  
11 occurred to me. And I'm sorry to interrupt the flow here  
12 and I may have missed it. But did DEA provide any guidance  
13 or have any input into how you determined your threshold  
14 requirements?

15                 THE WITNESS: Absolutely none. The DEA -- the DEA  
16 said, "You built the system. It's your system and your  
17 responsibility," essentially. So they didn't, they didn't  
18 provide any of the substantive guidance on how to --

19                 THE COURT: So you determined the way you  
20 established the threshold requirements completely on your  
21 own?

22                 THE WITNESS: There -- so when counsel asked me  
23 the question about the multiplication times three, to the  
24 best of my recollection, there was a DEA public -- I forgot  
25 what it's called -- Advisory Committee, Public Advisory

1 Committee whereby they came together and made some  
2 recommendations. We used that same kind of -- because it  
3 was on the DEA site, we sort of used it as a framework  
4 within which to make our decisions about thresholds.

5 THE COURT: I completely interrupted your flow  
6 there, Mr. Fuller.

7 MR. FULLER: You can interrupt any time, Judge.

8 THE WITNESS: You get to do that.

9 BY MR. FULLER:

10 Q. And the Court had a great question. The, the  
11 involvement of the DEA -- you referred to, I think,  
12 what's referred to as the chemical handlers; right?

13 A. Yes.

14 Q. And chemical handlers is designed based, I think you  
15 stated, on the Meth Act?

16 A. To the best of my recollection, yes.

17 Q. And it's designed to identify extraordinary orders of  
18 List I chemicals; is that right?

19 A. Yes, I believe that's accurate.

20 Q. So it's not necessarily applicable to controlled  
21 substances unless they contain List I chemicals.

22 A. It's not necessarily -- you're right. It is not  
23 necessarily applicable, but it does provide a reasonable,  
24 rational framework within which to begin a discussion or a  
25 thought process about how to develop such a system.

1       **Q.**   And that system is designed, or the chemical handlers  
2           is identifying extraordinary sizes of List I chemicals;  
3           correct?

4       **A.**   That is correct.

5       **Q.**   Okay. Let's change to -- so the QRA evaluation --

6       **A.**   Yes, sir.

7       **Q.**   -- determination has to be made at Cardinal as to  
8           whether an order is plausible and suspicious or not  
9           plausible and suspicious; correct?

10      **A.**   Yes.

11      **Q.**   And it, it's determined -- if the order is not  
12           plausible and suspicious, you set out the process that's  
13           going to occur; correct?

14      **A.**   Yes. And the only point that I would make note of is  
15           that the order was already blocked because it -- you know,  
16           in most instances because it had a threshold.

17      **Q.**   It blocked at the triggering mechanization we looked at  
18           earlier; correct?

19      **A.**   Yes, correct.

20      **Q.**   And then the suspicious order has to be reported to the  
21           DEA; is that right?

22      **A.**   Once you determine that it is suspicious, the order is  
23           reported to the Drug Enforcement Administration.

24      **Q.**   Sales is notified as well; right?

25      **A.**   That is correct.

1       **Q.**   And then the customer's terminated from purchasing  
2       controlled substances or in totality; right?

3       **A.**   In, in, in, in the operation of the system, we either  
4       did not let them purchase controlled substances or, you  
5       know, that controlled substance or other related controlled  
6       substances or in totality.

7               And in many instances, there were circumstances where  
8       we even cut off their non-controlled substance ability, the  
9       ability to order non-controlled substances.

10      **Q.**   Now, during your tenure, were you more focused on  
11       reporting suspicious customers as compared to reporting  
12       suspicious orders?

13      **A.**   No, we reported -- the regulatory requirement is to  
14       report suspicious orders, and we reported suspicious orders.

15      **Q.**   So you never -- strike that. So every customer that  
16       you reported during your time frame, you either terminated  
17       them from purchasing controlled substances or in totality;  
18       correct?

19      **A.**   I do not --

20               MS. MAINIGI: Objection. I think that misstates  
21       his testimony.

22               THE COURT: Can you rephrase the question, Mr.  
23       Fuller?

24               MR. FULLER: Sure.

25               THE COURT: I'll sustain the objection.

1 BY MR. FULLER:

2 Q. The process laid out here has the customer being  
3 terminated from purchasing controlled substances or in  
4 totality; correct?

5 A. That is the statement on the slide, yes.

6 Q. Let's turn to Page 126.

7 Now, this talks about proactive threshold analysis. Do  
8 you see that?

9 A. I do.

10 Q. And it gives us some of the reasons for increasing a  
11 threshold, does it not?

12 A. These, these characteristics could be characteristics  
13 associated with increasing the threshold.

14 Q. Okay. It says "Things You Do." It says "Our People."  
15 What does that mean?

16 A. The, the basic parameters around where we built the  
17 corporate-wide effort was Anti-Diversion is everyone's  
18 responsibility. So we built a team effort so our people --  
19 all of our people would be engaged in the process because it  
20 comes back to -- any system is three things, you know. A  
21 first semester MBA student knows it's people, process, and  
22 technology.

23 Q. Then it's "Know Your Customer." That's part of the  
24 process; correct?

25 A. Yes.

1       **Q.**   Gather information and provide to QRA, significant  
2       change in business. If there is a significant change, that  
3       would be a legitimate reason for changing the threshold?

4       **A.**   These are characteristics that would demonstrate a, a  
5       justification for a change in threshold.

6       **Q.**   First one being a new Hospice contract?

7       **A.**   Yes.

8       **Q.**   What that's referring to is if they gain a massive  
9       customer of some sort, that may be a legitimate reason to  
10      increase or change a threshold?

11      **A.**   It doesn't have to be a massive customer. It just has  
12      to be a change -- it's a change in their business that would  
13      be reflected in the prescriptions that doctors were  
14      prescribing that the pharmacy would be dispensing for  
15      patients which would obviously change the need to order  
16      controlled substances to meet and care for the patients that  
17      were in Hospice.

18      **Q.**   The next one is file purchase of another pharmacy;  
19      basically, where one pharmacy buys out another. Is that  
20      right?

21      **A.**   Yes.

22      **Q.**   Location change into the medical center, another reason  
23      to change or increase a threshold?

24      **A.**   They would be -- not necessarily reasons to increase a  
25      threshold, but they would be reasons to be looked at as to

1 why a threshold change might be necessary. In some  
2 instances, you might wait for the threshold to hit. Other  
3 instances, you may do a proactive analysis.

4 **Q.** And the final one listed is addition of a new cancer  
5 center; correct?

6 **A.** Yes, sir. It changes the dynamics of, you know, as I  
7 said earlier, the relationship of the pharmacy let's say to  
8 the hospital, and then the hospital builds a brand new  
9 cancer center and it acquires a different number of  
10 patients, and the patients are going to be treated  
11 differently.

12 **Q.** And in the validation process of QRA and keeping the  
13 due diligence file, you would want to see this type of  
14 documentation to support this kind of change?

15 **A.** Depending upon the circumstances and the time, you  
16 know, the timing of where we were in the process. The  
17 documentation would ordinarily be there for the pharmacist,  
18 and the team would use that, you know, evaluation, make the  
19 evaluation and make a change.

20 **Q.** Now let's go to Page 128. This is the decision impact,  
21 the impact of whatever decision is made by QRA?

22 **A.** Yes.

23 **Q.** If the order is justified, additional products from the  
24 original order may be released up to the new threshold  
25 amount. That's assuming there was a change in threshold or

1           an increase in threshold; right?

2         **A.**    It does make that assumption, yes.

3         **Q.**    And if that due diligence has been done, it would  
4           justify a basis for increasing the threshold, then they can  
5           order up to that order amount; is that right?

6         **A.**    Yes, sir.

7         **Q.**    Next point: If the threshold is not increased, the  
8           remaining of the product is cut from the original order --  
9           excuse me -- if the threshold is not increased, the  
10          remaining product from the original order will be cut. It  
11          means we keep the blocked order blocked.

12        **A.**    Correct. The order is blocked.

13        **Q.**    If the size of the original order is not justified, QRA  
14          will send the report to the DEA, or Drug Enforcement  
15          Administration, and a block will be applied to all families  
16          of controlled substances. Correct?

17        **A.**    That is what's stated there, yes.

18        **Q.**    Okay.

19                   MR. FULLER: Judge, I'm sorry. I moved that one  
20          into evidence already.

21          BY MR. FULLER:

22        **Q.**    P-1930. Mr. Mone, do you recognize -- let me ask  
23          you, do you recognize this document?

24        **A.**    The first page is an email from me on 10/1 of 2008 to  
25          Chris Anderson.

1       **Q.**   And who is Chris Anderson? Do you know?

2       **A.**   Okay. I learned from the last time I'm going to read  
3 what it says down below. He is the Director of Operational  
4 Excellence and Quality Systems.

5       **Q.**   There's always a good way to cheat a little bit, huh?

6       **A.**   Yeah.

7       **Q.**   All right. It says here -- you write to Chris, and  
8 this is October 1st of 2008, that, "I made a few changes to  
9 the slides and some information has changed a bit." Right?

10      **A.**   Yes, sir.

11      **Q.**   And you attached several documents -- well, actually, I  
12 think it's one PowerPoint presentation. Correct?

13      **A.**   The documents, I believe, originated with Chris.

14      **Q.**   Right. You're sending them back to him after you made  
15 some changes?

16      **A.**   Yes, yes.

17      **Q.**   And have you seen these slides before as well?

18      **A.**   I undoubtedly have seen these slides before, but I  
19 don't recall them currently, you know. It's 12 years ago.

20                    MR. FULLER: Your Honor, I would move into  
21 evidence Plaintiffs' 1930.

22                    THE COURT: Any objection to 1930?

23                    MS. MAINIGI: No objection, Your Honor, provided  
24 that the witness can corroborate a foundation. I note that  
25 there are some notes on the page in addition to the slides.

1       And the witness has testified that he's flipped through the  
2 slides. I don't know if he can corroborate the notes that  
3 are on the slides.

4       BY MR. FULLER:

5       **Q.**     Mr. Mone, let me ask a question. Mr. Mone, when  
6 you went through this, were you reviewing the totality  
7 of the PowerPoint?

8       **A.**     To the best of my recollection, I was reviewing my  
9 components of the slides.

10      **Q.**     And you made edits to those?

11      **A.**     Apparently, I did. What those edits were, I don't  
12 recall what they were.

13      **Q.**     Sure. You don't have an independent recollection today  
14 of what edits you made?

15      **A.**     Right.

16      **Q.**     But according to your statement in the email, you made  
17 edits and then you sent it back?

18      **A.**     Yes.

19                    MR. FULLER: Judge, I would move for the  
20 admission.

21                    MS. MAINIGI: Your Honor, I still don't think a  
22 foundation has been laid for the notes portion of the  
23 slides.

24                    THE COURT: Did you make the notes, Mr. Mone?

25                    THE WITNESS: I did not.

1                   THE COURT: Do you know who did?

2                   THE WITNESS: I do not.

3                   MS. MAINIGI: I'm fine with admitting it without  
4 the notes.

5                   THE COURT: Let's excise the notes and admit it  
6 without the notes. How about that, Mr. Fuller? Are you  
7 happy with that?

8                   MR. FULLER: Judge, I think he would have reviewed  
9 it, but that's fine. I don't have any objection.

10                  THE COURT: Okay. 1930 is admitted, but the Court  
11 will not consider the notes. They're not -- the notes are  
12 not admitted. The rest of the exhibit is admitted.

13                  MR. ACKERMAN: Your Honor, --

14 BY MR. FULLER:

15 **Q.** Mr. Mone, turn to Page 18 of the document.

16 **A.** Yes, sir.

17 **Q.** This is the idea of the mentality behind your system,  
18 isn't it? First we identify; correct?

19 **A.** Correct.

20 **Q.** That's through our triggering system?

21 **A.** Right.

22 **Q.** Then we block, meaning we can't ship the order; right?

23 **A.** That is a component of the triggering system.

24 **Q.** Then we have to conduct due diligence. And if we don't  
25 surpass the due diligence threshold, meaning clear the

1 order, then it has to be reported to the DEA?

2 **A.** If we determine that it is suspicious, it is reported  
3 to the DEA.

4 **Q.** If you turn to the next page. The methods of diversion  
5 that you were concerned about at Cardinal included several;  
6 correct?

7 **A.** Yes, sir. That's on the slide.

8 **Q.** Including indiscriminate prescribing; right?

9 **A.** That is a method of diversion, yes.

10 **Q.** Doctor shopping?

11 **A.** That is a method of diversion.

12 **Q.** Pain clinics?

13 **A.** Depending upon how you define pain clinics. I actually  
14 call them prescription clinics. But go ahead, yeah.

15 **Q.** Excessive orders and distribution.

16 **A.** Yes, sir.

17 THE COURT: What do you mean by financiers there  
18 as a method of diversion?

19 THE WITNESS: I have no idea because that wasn't  
20 my slide. My slides are --

21 THE COURT: Okay.

22 THE WITNESS: -- from 31, and not all of the ones  
23 after 31 are, are mine.

24 THE COURT: Okay.

25 BY MR. FULLER:

1       **Q.**    So your slides are up to --

2       **A.**    My slide starts on 31. And not all of the ones that  
3           follow 31 are my slides.

4       **Q.**    Okay.

5       **A.**    It's the one where my history and background is  
6           identified.

7       **Q.**    28038. Mr. Mone, do you recognize this document  
8           identified as Plaintiffs' 28038?

9       **A.**    I recognize -- do I recognize it?

10      **Q.**    Yes, sir.

11      **A.**    No.

12      **Q.**    Are you identified on it?

13      **A.**    I am identified on it.

14      **Q.**    And is this an email from Douglas Emma to multiple  
15           people, including yourself?

16      **A.**    I am a cc on the document, yes.

17      **Q.**    Do you have any reason to -- well, let me ask you this.  
18           Who is Douglas Emma?

19      **A.**    Doug Emma was one of the pharmacists on the QRA team,  
20           our, our Cardinal Health pharmacist QRA team.

21      **Q.**    And what was his role on the QRA team?

22      **A.**    He was a pharmacist that was part of the evaluation of  
23           the -- in the QRA team just like the other pharmacists who  
24           performed their evaluation on assessment of orders.

25      **Q.**    And is Mr. Emma sending this email to Mr. Linden Barber

1 and Mr. Gilberto?

2 **A.** He, he -- the two individuals were Linden Barber and  
3 Gilberto Quintero.

4 **Q.** And who are they, or what was their role?

5 **A.** Gilberto was the new -- well, at this time, not new  
6 anymore, but he's the new Mark Hartman. And Linden Barber I  
7 believe at this time was outside counsel.

8 **Q.** So, basically, Gilberto becomes your boss?

9 **A.** Gilberto was my boss, yes, sir.

10 **Q.** Okay.

11 MR. FULLER: Your Honor, at this time I would move  
12 in Plaintiffs' 28038.

13 THE COURT: Any objection to 28038?

14 MS. MAINIGI: Your Honor, just a hearsay  
15 objection. We're fine with this as long as it's not  
16 admitted for the truth.

17 THE COURT: Do you want to admit it for the truth?

18 MR. FULLER: Absolutely, Judge. It's an email  
19 from an investigator inside QRA reporting on what he does in  
20 QRA.

21 THE COURT: Okay. How do you get around the  
22 hearsay?

23 MR. FULLER: It's an admission, Judge. It would  
24 be 801(d)(2)(D), a statement made by the party's agent or  
25 employee on a matter within the scope of that relationship

1           while it existed.

2           THE COURT: It's admitted.

3           BY MR. FULLER:

4           **Q.** This email is on June 12th of 2012; is that right?

5           **A.** It is.

6           **Q.** Now, based on our timeline from the other documents  
7 admitted into evidence, we know that the Immediate  
8 Suspension Order was issued down in Lakeland in February of  
9 2012; correct?

10          **A.** That is correct.

11          **Q.** So this is while that issue is pending. Is that fair?

12          **A.** I don't recall when the issue was resolved. It may or  
13 may not be.

14          **Q.** Let me ask it differently. The issue with the second  
15 MOU had at least started when this email has occurred. It  
16 may have concluded. We just don't recollect?

17          **A.** I, I think that's a fair representation of what I  
18 remember.

19          **Q.** Okay. Let's walk through this. It says, "This is  
20 follow-up to a discussion we had on our conference call  
21 regarding the suspected hot spots, black hole cases, and  
22 cases that probably need to be revisited by LV-TAC." Right?

23          **A.** You read that correctly.

24          **Q.** And explain to the Court -- well, let me help you.  
25 LV-TAC is a special committee within Cardinal; is that

1 right?

2 **A.** It is a special committee that was created within  
3 QRA -- within Cardinal, yes, yes.

4 **Q.** And it was members of the QRA department; right?

5 **A.** Yes.

6 **Q.** And it would look at special instances or particular  
7 concerns; is that correct?

8 **A.** It would look at particular customers that were  
9 identified to be looked at because of their volume of  
10 controlled substances purchased.

11 **Q.** And LV stands for large volume, doesn't it?

12 **A.** It did, yes.

13 **Q.** Do you recollect who the members of that committee  
14 were?

15 **A.** I know that the, that the SVP, the SVP of QRA, the VP  
16 of QRA, and a bunch of folks. I apologize. I don't.

17 **Q.** Sure. Were you a member of that committee?

18 **A.** I was initially, yes.

19 **Q.** And was your boss a member, whether Mr. Quintero or Mr.  
20 Hartman?

21 **A.** Mr. Hartman has been retired, so it would be  
22 Mr. Quintero.

23 **Q.** Okay. And you're right. Let me back up. This  
24 committee was started somewhere around the beginning of  
25 2012; is that right?

1      **A.**    Sometime in 2012, yes, sir.

2 Q. Okay. So back when you originated or came into this  
3 position at QRA in Chapter 2, there was no LV-TAC?

**A.** That is correct.

5 Q. This came as a growth of the enforcement action down in  
6 Lakeland; correct?

7       **A.**     This came as an improvement in -- as I cite, we're  
8           continuously improving the program. This came in as an  
9           improvement to the program.

10 Q. Fair enough. It says next that, "I've taken the time  
11 to illustrate a few examples. Please contact me if you need  
12 anything further."

13 Now, is Mr. Emma one that would have access to a host  
14 of information related to all your pharmacies?

15       **A.**     Mr. Emma would have access to information that would --  
16                  in the ordinary course of what he did come in contact with.  
17                  How far broader than that may very well have been a function  
18                  of -- and I do not know -- participation in the LV-TAC.

19 Q. Now, the LV-TAC and as well as all of QRA, they weren't  
20 again limited in any particular geographic area that they  
21 were looking at; is that correct?

**A.** That is correct. It was the entire enterprise.

23 Q. When you say the entire enterprise, you mean the entire  
24 country?

**A.** Correct.

1       **Q.**    Okay. And they point out several issues here; correct?

2       **A.**    He, he raises several.

3       **Q.**    First are possible hot spots. Do you see that?

4       **A.**    I do.

5       **Q.**    That's dealing with hot spots out in Fresno,  
6 California, is one of them; right?

7       **A.**    Yes, sir.

8       **Q.**    Then he's talking about a Medicine Shoppe. Do you see  
9 that?

10      **A.**    Uh-huh.

11      **Q.**    Medicine Shoppe BT3743300?

12      **A.**    I do.

13      **Q.**    And Medicine Shoppe has a particular relationship with  
14 Cardinal; is that right? I believe you testified to that  
15 earlier.

16      **A.**    Medicine Shoppe is the brand name of a franchise  
17 operation for Cardinal Health.

18      **Q.**    And I'll represent to you that the evidence will show  
19 that there is a Medicine Shoppe in Cabell County -- well,  
20 actually in the City of Huntington that skirts out into  
21 Wayne County.

22                  MS. MAINIGI: Objection, Your Honor. I think Mr.  
23 Fuller is just testifying.

24                  THE COURT: Well, I'll overrule it. He's just  
25 laying the basis for the line of questions he's going to

1 pursue, so overruled.

2 BY MR. FULLER:

3 Q. Mr. Mone, the relationship that Cardinal has with  
4 Medicine Shoppe and the franchisees --

5 A. Uh-huh.

6 Q. -- Medicine Shoppe pays Cardinal a franchise tag, if  
7 you will, for becoming part of their system; correct?

8 A. My understanding of how franchises work, and I'm not a  
9 franchise expert, is that the franchisees pay the franchisor  
10 a fee for the ability to use the mark.

11 Q. And on top of that, Medicine Shoppe also pays for the  
12 pills that they order from Cardinal; correct?

13 A. If that Medicine Shoppe is a customer of Cardinal  
14 Health, they would obviously have an obligation to pay for  
15 the medicines that they order.

16 Q. And are you aware whether there's licensing -- I'm  
17 sorry.

18 A. I'm done.

19 Q. Are you aware whether there are licensing agreements  
20 between Medicine Shoppe and the different franchisees?

21 A. I, I am not aware of what the licensing agreements are.

22 Q. My question is very simply were you aware if they  
23 exist?

24 A. I have no independent knowledge that they exist, but  
25 logic tells you that in order to be a franchisee, there has

1 to be a licensing agreement.

2 **Q.** And I would assume, then, that you don't have any  
3 knowledge as to what control Medicine Shoppe has over the  
4 franchisees and where they order controlled substances or  
5 anything else from, or do you?

6 **A.** My only knowledge of the relationship is that Medicine  
7 Shoppe franchisees are treated as independent retail  
8 pharmacies.

9 **Q.** And that means treated differently than the national  
10 chains; is that correct?

11 **A.** Treated differently than chains, that is correct.  
12 They're treated just like every other retail independent  
13 pharmacy.

14 **Q.** All right. Then we get down to -- well, Midwest  
15 Benefit Pharmacy. That's another one listed here, correct,  
16 under the hot spot section?

17 **A.** Yes, sir.

18 **Q.** Then we get down to the black hole section. Do you see  
19 that?

20 **A.** I do.

21 **Q.** And there we list I believe it's just two pharmacies;  
22 right?

23 **A.** There are two pharmacies identified.

24 **Q.** Van Pharmacy in Van, West Virginia. Do you know where  
25 Van, West Virginia, is, Mr. Mone?

1       **A.**   I have no idea, none whatsoever.

2       **Q.**   Okay. And it says here, "QRA first discovered in  
3           January of 2012 that the pharmacy was filling out-of-state  
4           prescriptions from a pain clinic in Georgia."

5           Did I read that correctly?

6       **A.**   You did read that correctly.

7       **Q.**   Was that a known issue or concern at Cardinal that  
8           there may be migration of pills?

9           MS. MAINIGI: Objection, Your Honor, outside of  
10          geographic scope. The pharmacy is not in Cabell County.

11           THE COURT: Well, I'll overrule it. Go ahead.

12           THE WITNESS: Whenever a pharmacy was dispensing  
13          pursuant to prescriptions received from practitioners  
14          outside of their area, we would normally almost always make  
15          an inquiry into that.

16          BY MR. FULLER:

17       **Q.**   And not just in this particular instance, but that  
18          was a known concern for Cardinal. That was a potential  
19          red flag. Right?

20       **A.**   It was a, it was a consideration based upon the  
21          totality of the circumstances that we would look into.

22       **Q.**   And at least here in June we've known it's been going  
23          on at least as far back as January of 2012; correct? At  
24          least that's what the email says.

25           MS. MAINIGI: Objection, foundation. I don't

1 think that there -- it's been established that Mr. Mone has  
2 any knowledge of this besides Mr. Fuller just asking him to  
3 read the email.

4 THE COURT: I agree. Sustained.

5 BY MR. FULLER:

6 **Q.** Let's go down to T & J Enterprise doing business as  
7 Medicine Shoppe in Huntington, West Virginia. As I told  
8 you, the evidence would show there is a Medicine Shoppe  
9 in Huntington, West Virginia. Is that correct, Mr.  
10 Mone?

11 **A.** It appears based upon this email that there is a  
12 Medicine Shoppe in Huntington, West Virginia.

13 **Q.** And, again, keep in mind this is January of 2012.  
14 "This pharmacy has experienced significant growth from the  
15 stimulant drug families and new pain clinic business."

16 Do you see that there?

17 **A.** I see the statement.

18 **Q.** And one would presume that if we're seeing significant  
19 growth, we're going to see some sort of documentation of  
20 that in the due diligence files for Medicine Shoppe; right?

21 **A.** One would anticipate that there would be. And given  
22 that it's 2012, it's likely to be in the system.

23 **Q.** And then on top of that, we're talking about growth  
24 from pain clinics, which is another potential red flag, is  
25 it not?

1       **A.**     Only to the extent that we would make an inquiry  
2 because not all pain clinics are -- not all pain clinic  
3 physicians fail to meet their obligation to prescribe in  
4 good faith in the course of professional practice for a  
5 legitimate medical purpose.

6       **Q.**     And that's why we have to do due diligence to be able  
7 to make that determination; correct?

8       **A.**     We have to do due diligence to satisfy ourselves that  
9 the pharmacist in the dispensing of that medication is  
10 meeting their corresponding responsibility in assessing the  
11 prescriptions that the doctor is writing for the pain  
12 clinics.

13      **Q.**     And you would want to know what pain clinics they're  
14 servicing; right?

15      **A.**     We would want to, we would want to inquire who the new  
16 pain clinic was prescribing.

17      **Q.**     And you'd want to inquire as to the top prescribers,  
18 and particularly if they're coming from that particular pain  
19 clinic; right?

20      **A.**     We would look at the prescribers of the pain clinics.  
21 We -- I'm sorry. To the extent that the pharmacist who's  
22 making this analysis feels that it's relevant, which I would  
23 presume that they would, then, yes, the answer is they would  
24 look into that.

25      **Q.**     And just so we're clear, when we say the pharmacist,

1       we're talking about Cardinal's pharmacist, not the  
2       pharmacist in the pharmacy.

3       **A.**      Yeah. They have their own corresponding responsibility  
4       in the pharmacy, but our pharmacists would make inquiry.

5       **Q.**      And it says, "QRA vetted the new pediatrician  
6       prescribing stimulants and nothing significant appeared from  
7       a DEA and license search."

8                  Did I read that right?

9       **A.**      You did.

10      **Q.**      It says, "A competitor in town was raided by the DEA  
11       which resulted in the arrest of the non-pharmacist owner."

12                  Are you aware that there was a pharmacy in Huntington  
13       that was shut down by the DEA?

14      **A.**      To the best of my recollection, I, I do not have any  
15       specific knowledge that that occurred.

16      **Q.**      Okay. Now, is that an issue that Cardinal would want  
17       to be aware of?

18      **A.**      The easy answer for you is "yes" because, obviously, it  
19       was a concern for our pharmacist. Therefore, it is a  
20       concern about what to do with the prescriptions from that --  
21       patients who had been going to that pharmacy would naturally  
22       be going to other pharmacies in the area. So, yes, it's a  
23       relevant inquiry.

24      **Q.**      And if some of those patients were illegitimate  
25       patients, the pharmacy would get shut down, at least

1 according to this, by the DEA. We wouldn't necessarily want  
2 illegitimate patients coming to our customers. Correct?

3 MS. MAINIGI: Objection, Your Honor. This calls  
4 for speculation. We're not talking about this particular  
5 circumstance. I don't know what Mr. Fuller is talking about  
6 here.

7 THE COURT: Okay. Sustained.

8 MR. FULLER: I'll ask it a different way.

9 BY MR. FULLER:

10 Q. Is one of the concerns that you have related to a  
11 DEA shutdown of a pharmacy is where are those  
12 prescriptions now going to get filled?

13 A. Can you say the question again?

14 Q. Sure. I'll ask it again. When a DEA pharmacy or the  
15 DEA comes in and shuts down, raids a pharmacy --

16 A. Yes.

17 Q. -- in a small town, you're going to want to be mindful  
18 of that if you can be; correct?

19 A. When, when the DEA closes a pharmacy in any town, it  
20 doesn't have to be a small town, just a town, it is a  
21 relevant inquiry to, for the pharmacist to look at the post  
22 shutdown changes to our customers in that area.

23 Q. And, so, when you're evaluating such things as  
24 threshold breaches or even threshold adjustments, that's  
25 part of the totality of the circumstances that Cardinal

1       wants to use in trying to make those type of decisions?

2       **A.**     Cardinal would use those factors in the totality of  
3           the -- the pharmacists would use that in the totality of the  
4           circumstances in their evaluation.

5           THE COURT: Mr. Fuller, I'm going to pull the plug  
6           on this and attend to another matter. So when you get to a  
7           stopping point, we'll --

8           MR. FULLER: Judge, we can break right now.

9           THE COURT: Okay. That's fine. Let's come back  
10          at 2:00.

11          MR. FARRELL: Judge, may I make a quick proffer  
12          before we leave?

13          THE COURT: Yes.

14          MR. FARRELL: You previously, you previously ruled  
15          that P-45, lack of foundation, and provided the opportunity  
16          for the plaintiffs to find another avenue to introduce it.

17          Therefore, under Document 835, the stipulation in this  
18          case, it reads, "Plaintiffs will be provided an opportunity  
19          to cure all unresolved issues relating to authenticity and  
20          foundation, including the ability to depose and/or call a  
21          custodial witness at trial."

22          The custodial witness for P-45 is Steve Falk, F-a-l-k.  
23          We hereby place Cardinal on notice we intend to call him as  
24          a custodial witness for P-45.

25          THE COURT: Okay, all right. See you at 2:00.

1                             (Recess taken at 12:02 p.m.)

2                             THE COURT: All right, Ms. Hardin.

3                             MS. HARDIN: Good afternoon, Your Honor. Ashley  
4 Hardin on behalf of Cardinal Health.

5                             And I would just like to address the several  
6 accusations from this morning, including the comment by Mr.  
7 Farrell right before the lunch break that Cardinal Health is  
8 in breach of any of the evidentiary objections to which we  
9 have agreed. And I think this issue has come up this  
10 morning with regard to Document P-45.

11                            We are not in breach of any stipulation, Your Honor. I  
12 would like to clarify what those stipulations --

13                            THE COURT: Did he say you were? I don't remember  
14 that he said that.

15                            MS. HARDIN: That is certainly the impression I  
16 have been left with, Your Honor, and I think Mr. Majestro  
17 was also planning to address the Court.

18                            THE COURT: Okay.

19                            MS. HARDIN: And if that's incorrect, he'll  
20 clarify.

21                            First of all, the first stipulation that Cardinal  
22 entered into with regard to this issue is Docket 835. That  
23 was entered on August the 6th. And what we agreed to do in  
24 that stipulation, which didn't address any specific  
25 documents, that was to be worked out later. What we agreed

1 to do was for a certain set of documents to be agreed on  
2 later, not to object on authenticity and lack of sponsoring  
3 witness.

4 We also agreed that between the time the stipulation  
5 was entered on August the 6th of 2020 and start of the trial  
6 to work with the plaintiffs in good faith to address issues  
7 of authenticity and foundation.

8 We're now into the third and -- or fourth week of the  
9 trial and so, that time has passed. So, we do not agree  
10 that we have agreed to put up any -- any witness to cure any  
11 custodial issues.

12 And I think the statement was made this morning that  
13 they would like to send a subpoena to Steve Falk, who is the  
14 former General Counsel of Cardinal Health. We don't control  
15 him in any event, but even if we did, we wouldn't agree that  
16 it's proper to send a custodial deposition notice to him  
17 now.

18 But more fundamentally, Your Honor, the issues that  
19 were raised, the objections that were raised this morning do  
20 -- as to P-45 do not implicate the stipulation. We did not  
21 object to the admissibility of that document because it  
22 lacks authenticity or because they didn't have a proper  
23 sponsoring witness.

24 We objected to the admissibility of that document  
25 because it is hearsay and it is privileged. And in both --

1                   THE COURT: Well, I read all of these stipulations  
2 and you did reserve your right to --

3                   MS. HARDIN: Exactly, Your Honor.

4                   THE COURT: -- object on hearsay and a whole bunch  
5 of other stuff, too.

6                   MS. HARDIN: That's right. So, 835, as I said,  
7 was the original stipulation that didn't deal with any  
8 specific documents. Then there are three separate  
9 stipulations that got entered that actually do deal with  
10 particular documents on which we made that agreement on --  
11 on authenticity and lack of sponsoring witness.

12                  The one that concerns Document P-45 is Docket 1305 and  
13 the listing of exhibits is 1305.1. And it -- as Your Honor  
14 rightly notes, it couldn't be more clear. We said we  
15 preserve all evidentiary objections, including hearsay.

16                  We made a hearsay objection to the admissibility of  
17 that document and Your Honor sustained the objection. So,  
18 we're outside of the realm of the stipulation and we're  
19 outside of the realm of where any custodial witness, even if  
20 they could get a deposition, even if we agreed they could do  
21 that, would help them cure their issue.

22                  So, we're not in breach and we just wanted to make that  
23 abundantly clear to the Court, Your Honor. So, thank you  
24 very much.

25                  THE COURT: Okay. Thank you.

1                   Mr. Majestro, do you want to say something?

2                   MR. MAJESTRO: Yes, sir.

3                   So, Your Honor, I missed much of this morning's  
4 proceedings, but we had a discussion over lunch and I came  
5 up with what I think is a good -- a better way to handle  
6 this than we've been doing it in this case.

7                   With respect to the documents where the parties have  
8 stipulated to authenticity, where the parties have  
9 stipulated that there isn't a need to present the documents  
10 through a sponsoring witness, and that would include, I  
11 believe, the McKesson documents, and the Cardinal documents,  
12 and some third-party documents like the documents from the  
13 DEA, we would propose that the night before -- instead of  
14 what we've been doing is listing the documents to be used  
15 with witnesses and that -- I think that's what we're getting  
16 all bollixed up about, that we would just list those  
17 documents as documents we are going to tender to the Court  
18 and move for admission in the record.

19                  Now, the parties can list their objections like we've  
20 been doing. We can list our responses. We can submit our  
21 responses. We can submit them to the Court and if there are  
22 any hearsay objections or other issues that need to be dealt  
23 with, we can deal with them. Either the Court can rule or  
24 the Court -- if the Court wants to hear argument on them,  
25 but -- but this -- you know, we've gotten a lot of argument

1 over documents that we don't think we need to be doing that.

2 I don't -- I think I went to sleep dreaming of  
3 802(1) (D) last night and there's no need to do that in  
4 court. And so, so we propose that that be the case. That's  
5 what we are going to do tonight. We wanted to provide the  
6 defendants with notice.

7 Now, I understand ABDC is objecting to that because  
8 their witnesses are gone and the stipulation was limited to  
9 production through the witnesses that showed up. That, I --  
10 I haven't looked at that stipulation. If that's the case,  
11 we won't identify ABDC documents.

12 But these other documents are documents that the  
13 stipulations either through third parties where all the  
14 defendants agreed to or the remaining two defendants with  
15 live witnesses where they have agreed that we don't need a  
16 sponsoring witness, we don't need to be arguing about those  
17 documents with witnesses on the stand.

18 THE COURT: Your stipulations were just with  
19 Cardinal, weren't they?

20 MR. MAJESTRO: There is a separate stipulation  
21 with McKesson and then -- for their documents and there is a  
22 stipulation with all the defendants for docs -- for other  
23 third-party documents, such as DEA documents, and those  
24 kinds of documents. And those are the -- those are the  
25 documents that I am proposing we follow this procedure on.

1                   THE COURT: Mr. Mahady?

2                   MR. MAHADY: Your Honor, Mr. Majestro  
3 distinguished, I believe, between the stipulations of the  
4 other defendants and the ABDC stipulation. I just want to  
5 make note for the record that there is a distinction as far  
6 as we're concerned. I can deal with that with Mr. Majestro.  
7 If he feels like he needs to raise it later, he can.

8                   MR. MAJESTRO: Yeah, and I haven't looked at -- I  
9 pulled up the McKesson stipulation and I'm assuming they all  
10 three had the same language. He raised that same issue  
11 immediately before. We'll work that out.

12                  We won't -- if there is not a -- if there's not an  
13 agreement that the document can be produced without a  
14 sponsoring witness or if there's some other agreed -- you  
15 know, some other way to get it in without a sponsoring  
16 witness, we're not going to put them on the list that way.  
17 We'll put them on the list of witnesses, but as he pointed  
18 out, his witnesses are gone, so they're not going to be his  
19 witnesses.

20                  MR. MAHADY: Right. And, Your Honor, I'll just  
21 note that what the stipulation says is that  
22 AmerisourceBergen stipulates that they will not object to  
23 the presentation of these documents through Chris Zimmerman,  
24 Steve Mays, David May and/or Michael Perry at trial while  
25 preserving all other evidentiary objections.

1           That was a negotiated term. I believe the plaintiffs  
2 sought to have no sponsoring witness. We negotiated that it  
3 has to be through those witnesses. Those witnesses have now  
4 come and gone.

5           So, our position is, is that the plaintiffs cannot now  
6 seek to move in additional documents, whether stipulated or  
7 not, without these witnesses per the stipulation.

8           THE COURT: Well, let's wait until the documents  
9 are offered and then -- then deal with that at that point,  
10 Mr. Mahady.

11           MR. MAHADY: Thank you, Your Honor.

12           THE COURT: Mr. Hester?

13           MR. HESTER: Your Honor, I'm just not sure how the  
14 procedure that Mr. Majestro is proposing would, in fact,  
15 work. If it's all going to be by paper, there's no  
16 opportunity for us to present our views to the Court in any  
17 realistic methodology and, furthermore, I'm not sure how we  
18 would determine what the Court has admitted into evidence  
19 and what it's not. It feels like it's shifting some work to  
20 the Court here; whereas, the way we've been doing it, I  
21 understand there's been a little bit of back and forth, but  
22 in the aggregate, it's useful for us to know what's in  
23 evidence as we're going through the testimony on particular  
24 days.

25           THE COURT: Well, some of the problem was probably

1 my fault because I didn't perfectly understand the  
2 stipulations. I've read them now and I think that I do.

3 So, Mr. Majestro, I think we can just deal with it as  
4 it comes up.

5 MR. MAJESTRO: Okay. So, we'll put them on the  
6 list and we'll see what happens.

7 THE COURT: Mr. Farrell?

8 MR. FARRELL: I think that cures everything except  
9 for P-45. P-45 is the audit and, this morning, there was an  
10 objection on foundation, which you sustained.

11 So, we're perfectly willing and able and encourage a  
12 discussion on hearsay grounds, but the objection that was  
13 sustained -- that was made and sustained, according to my  
14 learned co-counsel, was on foundation. So, the problem that  
15 we have is that if, in fact, we're going to have foundation  
16 arguments, then we only have a finite number of Cardinal  
17 Health witnesses in order to present it through.

18 THE COURT: Well, doesn't the stipulations take  
19 care of the foundation argument? And that may -- I don't  
20 remember that specific document.

21 MR. FARRELL: Yes, Your Honor.

22 THE COURT: But --

23 MS. HARDIN: Your Honor, I think we are perhaps  
24 confusing -- can you hear me -- confusing two issues.

25 We objected to the admissibility of P-45 on hearsay

1 grounds and it's certain we don't have access to the  
2 transcript at this point in time, but we understood that  
3 that was the objection that Your Honor sustained and why  
4 that document is not admissible.

5 We made a foundation objection to whether or not Mr.  
6 Mone is capable of testifying about that document, whether  
7 or not it comes in. The answer to that is lack of  
8 foundation because he testified that he -- I believe he  
9 testified that he had never seen it. So, that was the  
10 foundation objection. No custodial deposition could cure  
11 that.

12 THE COURT: So, you're saying that the stipulation  
13 makes it admissible, but there's no foundation for Mr. Mone  
14 to testify?

15 MS. HARDIN: No, sir. We don't believe the  
16 stipulation makes P-45 admissible. We -- the stipulation  
17 says we're not going to object to P-45 on the ground of  
18 authenticity, so we don't contend that it's not authentic,  
19 and we don't contend that they have to put up a sponsoring  
20 witness.

21 So, if P-45 were independently admissible, then it  
22 could come in theoretically through Mr. Mone, but Mr. Mone  
23 cannot testify about it because he has no foundation from  
24 which to do so. And here, in this particular instance, the  
25 document is not independently admissible because it is

1       hearsay and the plaintiffs have not overcome the hearsay  
2       objection. Your Honor sustained that objection.

3            MR. ACKERMAN: Your Honor, may we make a record on  
4       the hearsay objection because I don't believe a record has  
5       been made on that objection.

6            MR. FARRELL: That's my point, Judge. The  
7       stipulation isn't limited to a sponsoring witness. The  
8       stipulation says foundation. We were prevented from asking  
9       any questions on foundation and that was the objection.

10          So, to be clear, what we're suggesting is that Mr. Mone  
11       says he's never seen this document before. We agree that  
12       precludes us from asking him questions on a document he has  
13       no knowledge of. It does not preclude us from tendering  
14       that document to the Court for admission.

15          What we're suggesting is that this process could be  
16       expedited and the witness testimony truncated if we come up  
17       with a procedure where we can take documents that we believe  
18       are subject to stipulation and tender them to the Court as  
19       if this were an appellate case submitted on the briefs.

20          There are documents we can submit on their face that  
21       will save us a tremendous amount of time and argument having  
22       to present it during an individual witness's testimony.

23          That being said, we have a pretty good argument of why  
24       this document, which was prepared at the request of, in the  
25       custodial file of, argued and briefed and even subject to

1 deposition testimony is not hearsay.

2 Now, one real quick side-bar. The defendants have also  
3 gone and made the argument that this document is subject to  
4 attorney-client privilege and I would like to proffer for  
5 the record that in the MDL 2804, ECF 1498, discovery ruling  
6 14.5, it specifically rejects attorney-client privilege and  
7 that it was affirmed by Judge Polster at ECF 1553.

8 So, to the extent that the defendants are trying to  
9 preserve for the record that this document is covered by  
10 attorney-client privilege, we believe there's been an  
11 insufficient showing to invoke the privilege.

12 THE COURT: Okay. Which one is it? What's the  
13 number on it? I will try and find it here.

14 MR. ACKERMAN: P-45.

15 THE COURT: P-45?

16 MR. ACKERMAN: Yes, sir.

17 MS. HARDIN: Your Honor --

18 THE COURT: Let me --

19 MS. HARDIN: Sure. Certainly.

20 THE COURT: Okay, I've got it now.

21 MR. ACKERMAN: So, Your Honor, with respect to the  
22 hearsay objection, this is a document that states on it --  
23 the first line of the letter says, "I have attached for your  
24 information and review our initial findings and  
25 recommendations on Cardinal Healthcare's Suspicious Order

1 Monitoring System." It is similar, if not identical, at  
2 least in analysis, to the FTI report that Your Honor ruled  
3 was not hearsay with regard to ABDC.

4 The reason that it is not hearsay, Your Honor, is  
5 because it falls within an opposing party's prior statement  
6 within Rule 801(d)(2) and, specifically, it is 801(d)(2)(C),  
7 a statement made by a person whom the party authorized to  
8 make a statement on the subject. Cardinal Health hired  
9 Cegedim Dendrite and authorized them to investigate and  
10 report their findings on its Suspicious Order Monitoring  
11 System.

12 It also is not hearsay pursuant to Rule 801(d)(2)(D),  
13 as in Delta, because it is a statement made by the party's  
14 agent on a matter within the scope of that relationship and  
15 while it existed. And I do believe that you stated with  
16 respect to ABDC that FTI was their consultant and their  
17 agent for purposes of this review. The same analysis  
18 applies with respect to this document.

19 THE COURT: Ms. Hardin?

20 MS. HARDIN: Your Honor, we disagree on both  
21 counts. One, Ms. Mainigi was clear this morning that this  
22 document was subject to an adverse privilege ruling against  
23 us in the MDL. We fought tooth and nail to have to produce  
24 this document. We lost that battle.

25 But now, here we are at the moment of truth. This is

1       the trial. And it's now wanting to be offered against us  
2 and admitted against us. And so, we do not waive our  
3 privilege objection. We have never waived that objection.  
4 And we assert it here again to the extent that this is the  
5 first time this document is ever being utilized against us  
6 in a court. So, that's point one.

7           Point two, this document does not fall within the  
8 hearsay exception. 801(2)(d)(C) -- I don't know if I'm  
9 getting all the letters confused -- is a statement of an  
10 agent.

11          In the -- the Fourth Circuit has addressed two times  
12 whether or not a party's lawyer's statement can be admitted  
13 against them under this exception and both times both  
14 statements involved a statement that the lawyer made to  
15 someone else in the outside world.

16          This report is legal advice. It is Cardinal Health's  
17 lawyer talking to it in a privileged attorney-client  
18 communication. They are not acting as our agent in that  
19 situation in terms of making statements on our behalf, nor  
20 did we authorize them to make any statements on our behalf  
21 to anyone else.

22          And so, if the exception is going to be that legal  
23 advice given within the confines of the attorney-client  
24 communication can then be entered against that party at  
25 trial, then I submit that is beyond anything that we have

1       seen in the case law in the Fourth Circuit and it's not what  
2       is contemplated by that exception, nor is this our own  
3       statement that we have adopted in any sense.

4           I mean, again, this is legal advice. And the legal  
5       advice was given to us just the same as if I call my client  
6       this afternoon and I give them my opinion about how this  
7       trial is going. That is not an admission of my -- that will  
8       not be an admission of my client. That will not be my  
9       client's statement. That would be my statement to my  
10      client.

11           So, it is hearsay. It's an out-of-court statement that  
12       they want to offer for the truth and they haven't yet given  
13       a proper hearsay objection, anything to override the hearsay  
14       objection, in our opinion, Your Honor.

15           MR. ACKERMAN: So, Your Honor, let me address that  
16       briefly. First of all --

17           THE COURT: I've heard enough of this. I'm going  
18       to stick with my original ruling, but I will take another  
19       look at it and see if it ought to be reversed, but I know  
20       what the arguments are here.

21           And I will consider your arguments, Mr. Ackerman.

22           MR. ACKERMAN: Okay.

23           THE COURT: And we've spent a half-hour almost on  
24       this and we need to get rolling.

25           Mr. Mone, are you here?

1 MS. MAINIGI: We're going to get him, Your Honor.

2 MR. ACKERMAN: While he is walking in, Your Honor,  
3 this -- and Cegedim Dendrite is not a law firm. I just want  
4 to make that clear for the record.

5 THE COURT: Well, he's a lawyer, isn't he, isn't  
6 he or she, or whoever it is?

7 MR. ACKERMAN: No, Your Honor.

8 MS. HARDIN: Your Honor, I believe --

9 MR. ACKERMAN: This is -- this is a third party  
10 that was hired by Cardinal Health.

11 THE COURT: Well --

12 MR. ACKERMAN: I understand and perhaps we should  
13 brief this or discuss it later.

14 THE COURT: Mr. Mone, you may resume the witness  
15 stand and you're under oath, of course, still under oath.

16 MR. FULLER: May I approach the witness?

17 THE COURT: You may, Mr. Fuller. Yes, you may.

18 BY MR. FULLER:

19 Q. I'm handing the witness what has been marked Plaintiffs  
20 7509. Mr. Mone, do you recognize this document? Let's  
21 start with the first page.

22 A. The first page -- sorry. The first page is an e-mail  
23 from Nick Rausch to me and others.

24 Q. And does it -- what does it pertain to?

25 A. It is a visual description of last month's SOM Report

1 with relevant metrics.

2 Q. This e-mail was sent on June 5th of 2009?

3           **A.** Yes, sir.

4 Q. And it mentions it was relating to the prior month. Is  
5 this something that you would get on a semi-regular basis?

6           **A.**       Yes, sir.

7 Q. And is this something that was done in the normal  
8 course of your employment as the one in charge of running  
9 the ORA Division at Cardinal?

10           **A.** Yes, it would.

11 Q. And was it Mr. Rausch's duty as -- or his position to  
12 send these e-mails to your group on a regular basis, as  
13 well?

14 A. Yes. He was in charge of the Analytics Group.

15 MR. FULLER: Your Honor, we would move in P-7509.

16 MS. MAINIGI: No objection, Your Honor.

17 THE COURT: It's admitted.

**PLAINTIFF EXHIBIT P-7509 ADMITTED**

19 BY MR. FULLER:

20 Q. And if we turn to the second page, this provides sort  
21 of a summary of the prior month, as well as a lookback,  
22 correct, Mr. Mone?

23           **A.**     It does.

24 Q. And so, if we look at the upper left-hand box, it says,  
25 "SOMS events per month". Do you see that?

1       **A.**   I do.

2       **Q.**   And that means suspicious order monitoring events for  
3           the month; is that correct?

4       **A.**   It refers to the threshold events per month.

5       **Q.**   And as we established earlier, that's particularly  
6           based off of volume, right? It has to hit that threshold  
7           trigger, correct?

8       **A.**   Those are the events that hit the threshold. Those are  
9           the events of the orders that hit the threshold.

10      **Q.**   And that, again, would only be considering volume; is  
11           that right?

12      **A.**   It's predominantly volume, yes.

13      **Q.**   Then there may be an analysis done related to frequency  
14           and pattern, but that's done by your pharmacist after the  
15           triggering event occurs?

16      **A.**   Both before and after.

17      **Q.**   And it looks back, what, about 12 months?

18      **A.**   It does.

19      **Q.**   And it provides numbers. So, 421 for June of '08, do  
20           you see that?

21      **A.**   I do.

22      **Q.**   Would that mean that Cardinal nationwide had 421  
23           triggering events across the country?

24      **A.**   Yes, it does.

25      **Q.**   And if we go to the next month, July, 390 -- excuse me.

1       793, do you see that?

2       **A.**   That is correct.

3       **Q.**   And that would mean we have 793 threshold triggering  
4           events under your system across the country?

5       **A.**   That is what that number means to me, yes.

6       **Q.**   If you turn to the last page, the third page, I'm  
7           sorry, there's another box there that refers to suspicious  
8           orders per month. Do you see that box?

9       **A.**   I do.

10      **Q.**   And is that the number of orders that Cardinal actually  
11           determined to be suspicious across the country?

12      **A.**   Yes.

13      **Q.**   So, if we look at that and we compare June of '08, we  
14           know we have 421 triggering events, right?

15      **A.**   Yes.

16      **Q.**   And we reported 12 suspicious orders; is that correct?

17      **A.**   That is correct.

18      **Q.**   So, for example, on July of '08, we had 793 triggering  
19           events, but only reported two orders nationwide.

20      **A.**   That is correct.

21      **Q.**   And carries on throughout the rest of the 12-month span  
22           there; is that right?

23      **A.**   It does.

24      **Q.**   Okay. And, again, this was the system that was housed  
25           in Dublin, Ohio; is that correct?

1           **A.** Yes, sir.

2 Q. So, Mr. Mone, I passed you two more documents. One is  
3 marked Plaintiffs' Exhibit 77 for the record. The other one  
4 is marked Plaintiffs' Exhibit 44267. Do you have them in  
5 front of you?

6           **A.**       I do.

7 Q. Are they the similar type of monthly summaries?

**A.** They are.

9 Q. And if you look at P-77, does it appear that in the  
10 upper right-hand corner that it's for a February, 2009  
11 summary?

12           **A.**     It does.

13 Q. And if you look at 44267, upper left-hand corner, it  
14 looks like it's for an August of 2009 summary, correct?

15      **A.**    Right.

16 Q. And these, again, were documents that were produced in  
17 the regular course of business in the Anti-Diversions  
18 Department?

19           **A.**     They were.

20 MR. FULLER: Your Honor, I would move in  
21 Plaintiffs' 77 and Plaintiffs' 44267.

22 MS. MAINIGI: No objection, Your Honor.

THE COURT: Admitted.

24 PLAINTIFF EXHIBIT 77 & 44267 ADMITTED

25 BY MR. FULLER:

1       **Q.**     Mr. Mone, did you use these to monitor how the system  
2                  was functioning?

3       **A.**     These were tools that were used by the team to make  
4                  assessments of the program.

5       **Q.**     And then, these are all based off the thresholds,  
6                  correct?

7       **A.**     These reports are based off of threshold, that is  
8                  correct.

9       **Q.**     Now, we talked about setting the thresholds earlier and  
10                 you're setting them, at least initially, end of 2007,  
11                 beginning of 2008, correct?

12      **A.**     That was the initial thresholds setting process, yes.

13      **Q.**     Before your arrival, Cardinal didn't use these type of  
14                 thresholds, right? They used Ingredient Limit Reports?

15      **A.**     Before I got there, Ingredient Limit Reports were being  
16                 -- were done and when I got there, they were already -- the  
17                 system was already in the beginning stages of making  
18                 adjustments to an electronic system.

19                 I don't recall how -- I don't recall how those initial  
20                 orders, you know, that they were establishing in the  
21                 immediate term before I got there were done.

22      **Q.**     But you implemented this threshold system we've been  
23                 talking about today?

24      **A.**     I improved -- I improved the entire -- I would like to  
25                 think I improved the entire system that was there.

1       **Q.**   And so, when you devised how these thresholds were  
2           going to be set using the system we talked about earlier,  
3           subcategorizing the customers, then subcategorizing them on  
4           size, then determining an average and tripling it, what did  
5           you do to take into consideration that the company was in  
6           the throes of an opioid epidemic?

7       **A.**   The considerations that we made were to take our  
8           assumptions that we were making in terms of where to place  
9           those thresholds and bounce those up against external  
10          experts to make certain that the assumptions that we were  
11          making were -- were appropriate.

12       **Q.**   And then that led you to the conclusion that it was  
13          still a good idea to multiply the average by three?

14       **A.**   Yes. When we sent -- when we sent it out and had  
15          external folks look at the process, they came back with an  
16          assessment with the assumptions that we were making were  
17          appropriate.

18       **Q.**   Now, we've talked about the thresholds. We've talked  
19          about that they're tracked. You guys had a -- and I said  
20          you guys. I'm sorry. Cardinal had an electronic system for  
21          tracking these thresholds and I think you testified earlier  
22          these were kept in the normal course, correct?

23       **A.**   That is correct.

24       **Q.**   You also tracked threshold changes in the normal  
25          course; is that right?

1       **A.**     Through system track changes, we did.

2       **Q.**     You had access to these systems?

3       **A.**     I did have access to the systems, yes.

4       **Q.**     As well as the rest of your team; is that right?

5       **A.**     Absolutely.

6       **Q.**     Now, not only with threshold changes, but threshold  
7 events. We see here that on certain months, for example,  
8 May of '08, we have the 421 threshold events. Those are  
9 tracked, as well, correct?

10      **A.**     Which document are you referring to?

11      **Q.**     I'm sorry. I'm on 7509, the one that has your e-mail  
12 attached to it.

13      **A.**     Okay, thank you. 7509? And what was your statement --  
14 question?

15      **Q.**     Yes, sir. I'll ask the question again. Where we have  
16 June of '08 the 421 threshold events --

17      **A.**     Yes.

18      **Q.**     Those are also tracked within Cardinal's system; is  
19 that right?

20      **A.**     Yes, they were.

21      **Q.**     Those were also accessible by you?

22      **A.**     Pardon?

23      **Q.**     You also have access to those?

24      **A.**     I did.

25      **Q.**     No longer?

1       **A.**    Correct.

2       **Q.**    You did at the time?

3       **A.**    Correct.

4       **Q.**    Your team had access to those?

5       **A.**    They did.

6       **Q.**    It's something that your department would use on a  
7                  regular basis in maintaining the anti-diversion system,  
8                  correct?

9       **A.**    Yes, they would.

10      **Q.**    You also tracked all the suspicious orders that were  
11                  reported, correct?

12      **A.**    Yes, we did.

13      **Q.**    You could look up and see how many suspicious orders  
14                  were reported in certain geographic areas, as well as  
15                  particular pharmacies; is that right?

16      **A.**    Yes, we could.

17      **Q.**    You had access to that system?

18      **A.**    Undoubtedly, I had access to the system. I'm not sure  
19                  I knew the ability to extract that information out of the  
20                  system.

21      **Q.**    That may be something that you asked one of your other  
22                  team members --

23      **A.**    Yes.

24      **Q.**    -- to pull for you; is that fair?

25      **A.**    Yes.

1           **Q.**     Okay.

2                   MR. FULLER: Your Honor, at this time, I would  
3 like to move in P-14294. We disclosed this last night and  
4 there was no objection.

5                   MS. MAINIGI: We have no objection, Your Honor, to  
6 its admission. Obviously, we can -- if it's something he's  
7 going to question the witness on, we can take that piece of  
8 it up as it goes, but we have no objection to its admission.

9                   THE COURT: Okay, it's admitted.

10                  **PLAINTIFF EXHIBIT P-14294 ADMITTED**

11                  MR. FULLER: Your Honor, I'm going to test my  
12 luck. I'm going to move for admission of P-44275.

13                  MS. MAINIGI: Same position, Your Honor.

14                  THE COURT: Admitted.

15                  **PLAINTIFF EXHIBIT P-44275 ADMITTED**

16                  MR. FULLER: And I would move for admission of  
17 P-42071.

18                  MS. MAINIGI: One moment, Your Honor.

19                  THE COURT: Yes.

20                  (Pause)

21                  MS. MAINIGI: Same position, Your Honor.

22                  THE COURT: All right. It's admitted.

23                  **PLAINTIFF EXHIBIT 42071 ADMITTED**

24                  BY MR. FULLER:

25                  **Q.**     Mr. Mone, a moment ago when we were talking about the

1 design of the thresholds and taking into consideration the  
2 epidemic, you mentioned relying on third-party experts.  
3 What third-party experts would that be?

4 **A.** Well, we subjected our SOM program to Deloitte. We  
5 subjected elements of it to IBM Watson. There were  
6 improvements that we looked at and we submitted to a Ph.D.  
7 at Ohio State. There may, in fact, be more, but those are  
8 the three I can think of right now.

9 **Q.** Now, let me try to inquire on those. The submission to  
10 Ohio State came further on in the system, correct?

11 **A.** It did.

12 **Q.** The submission to Cegedim Dendrite was earlier on in  
13 the system, correct?

14 MS. MAINIGI: Objection. I don't think that is  
15 the testimony. I don't think Mr. Mone said Cegedim  
16 Dendrite. He said IBM Watson, he said Deloitte, and he said  
17 Ohio State.

18 THE COURT: Sustained.

19 BY MR. FULLER:

20 **Q.** Mr. Mone, I'm handing you what's marked for  
21 identification purposes as Plaintiffs' Exhibit 80. Have you  
22 seen this document before?

23 **A.** I have not.

24 **Q.** You had -- do you have any understanding of what this  
25 Investigative Demand Committee Report would be?

1       **A.**     No.

2       **Q.**     Sure.

3       **A.**     May I -- may I make a correction?

4       **Q.**     Sure.

5       **A.**     Because I'm just not certain. I may actually have seen  
6 parts of this document in a prior deposition, but I haven't  
7 seen the document, the whole thing.

8       **Q.**     Fair enough. So, you may have recollection of this  
9 document from a prior deposition; you don't remember seeing  
10 it during the course of your employment?

11      **A.**     I do not. Do not.

12      **Q.**     Do you remember whether in the beginning of -- end of  
13 2012, beginning 2013, whether there was an investigation  
14 conducted related to the SOMS systems at Cardinal?

15      **A.**     I recall a -- for lack of a better term, I recall an  
16 internal -- an internal inquiry into the Suspicious Order  
17 Monitoring Program.

18      **Q.**     And were you interviewed related to that process?

19      **A.**     To the best of my recollection, I was.

20      **Q.**     Do you believe some of your team members may have been  
21 interviewed in that process?

22      **A.**     Undoubtedly, they were, more than likely.

23      **Q.**     And was that looking at and reviewing the SOMS system  
24 in place and any potential changes that may need to be made?

25      **A.**     I would assume that's what they were looking at.

1                   MR. FULLER: Your Honor, at this point, I would  
2 move into evidence -- not to show the witness -- but just  
3 submission into evidence, Plaintiffs' Exhibit 80.

4                   MS. MAINIGI: Your Honor, objection. I understand  
5 it's not being submitted to show the witness, so I will  
6 reserve on a foundational objection.

7                   My main objection to admission is geographic scope  
8 because this report relates to Florida-Lakeland. It does  
9 not report -- it doesn't have anything to do with  
10 Cabell-Huntington.

11                  THE COURT: Mr. Mone, what's the Special Demand  
12 Committee?

13                  THE WITNESS: I have no idea what that is.

14                  THE COURT: Oh, you don't know? Okay.

15                  MS. MAINIGI: I don't think -- I think, as he  
16 testified, Your Honor, he had not seen this. So, he -- he  
17 certainly may have been interviewed, but he doesn't know  
18 what the report actually says or what it covers. And our  
19 objection relates to the fact that this has nothing to do  
20 with Cabell and Huntington. It has to do with Lakeland,  
21 Florida.

22                  THE COURT: Well, I'm still not clear on exactly  
23 what this is, Mr. Fuller.

24                  MR. FULLER: Your Honor, and the Court can feel  
25 free to review the document. It is an investigation and a

1 report about the SOMS systems of Cardinal Health up and to  
2 the beginning or -- beginning of 2013, end of 2012, that was  
3 requested by the Board of Directors of Cardinal Health. It  
4 sets out not only Lakeland, Florida. It talks about their  
5 systems in general, and the national scope of those systems,  
6 and how they function, and what problems they had with those  
7 systems.

8 As Mr. Mone testified, he believes there was an  
9 internal investigation. All of this would throw it into  
10 801(d)(2)(A), (d)(2)(B), or (d)(2)(C).

11 MS. MAINIGI: Your Honor, we're not objecting on  
12 the basis of hearsay. We're objecting on the basis of  
13 geographic scope.

14 THE COURT: Well, I think it might be -- for the  
15 reason that I admitted the documents this morning that you  
16 objected to on geographic scope, I think it may relate to  
17 the -- to the overall program and whether it was working  
18 properly and so forth. I can't remember the term that was  
19 used this morning, can you, Mr. --

20 MR. FULLER: I'm sorry. I couldn't hear you, Your  
21 Honor.

22 THE COURT: The term that was used this morning --

23 MR. FULLER: The systemic failures?

24 THE COURT: Right. I think it relates to that and  
25 I'm going to admit it.

**PLAINTIFF EXHIBIT 80 ADMITTED**

BY MR. FULLER:

Q. Mr. Mone, as of the time of the 2008 memorandum agreement, was Cardinal required to centrally report all of its suspicious orders?

A. It was required to report to the DEA Office, as opposed to the obligation that individual distribution centers were required to report to their local -- you know, the regulations report locally and our MOA says report centrally.

Q. When we say report centrally, you guys -- I'm sorry. When we say report to the office, you at Cardinal had to report to Washington and the DEA Office, correct?

A. That is correct.

Q. And that's something that you helped to put in place and your team developed to put into place that this automated or electronic reporting would be done, correct?

**A.** Yes. The IT individuals at Cardinal Health were designing the reporting component of the obligation imposed by the MOT.

MR. FULLER: So, if we might, because it's been admitted, put up P-42071. It's an Excel spreadsheet.

BY MR. FULLER:

Q. Mr. Mone, I'll represent to you that this has been produced -- and it should be on the screen in front of you.

1        You don't have to look way over here.

2        **A.**     Okay.

3        **Q.**     As suspicious orders into what we call CT2, but into  
4                   Huntington-Cabell County, West Virginia, okay?

5        **A.**     All right.

6        **Q.**     And it has certain columns and I want to run through  
7                   with you what these are. A SOR ID, which is Column A, that  
8                   would be Suspicious Order ID?

9        **A.**     I have no idea what that is.

10      **Q.**     Let's keep going. Registrant, DEA, what do you suspect  
11                   that is?

12      **A.**     That one's fairly obvious. That's the registrant's DEA  
13                   number.

14      **Q.**     Fair enough. NDC, can you explain to the Court what an  
15                   NDC code is?

16      **A.**     Yes. The National Drug Code is the code that is  
17                   assigned to particular products by the manufacturer that  
18                   identify the product and the package size. So, the National  
19                   Drug Code.

20      **Q.**     So, if you have the NDC code for something you can  
21                   identify who made it, the strength, the type of drug it is  
22                   and how many come in a package, right?

23      **A.**     Yes, sir.

24      **Q.**     Then you have the order quantity, which that's pretty  
25                   self-explanatory. And then you have the limit order

1 quantity. And you have the number of records. Customer DEA  
2 number, is that the same as the registrant DEA number?

3 **A.** Actually, no. Now that we're -- now that I'm looking  
4 at this, the first registrant DEA number would be our  
5 registration number.

6 **Q.** So, potentially, if Wheeling was distributing to  
7 Cabell-Huntington, that would be the DEA registrant number  
8 for the Wheeling Distribution Center; is that correct?

9 **A.** That is a -- that is a distribution registration  
10 number. I don't know to whom it applies. More than likely,  
11 it applies to Wheeling, but that's -- I apologize for my  
12 error before.

13 **Q.** No, that's all right.

14 MR. FULLER: If we could slide over Gina.

15 BY MR. FULLER:

16 **Q.** And we have the customer name, T and J Enterprises.  
17 Customer address, doing business as Medicine Shoppe. We  
18 continue over. It's in Huntington, West Virginia. Drug  
19 family?

20 **A.** Yes.

21 **Q.** We've talked about that a little bit earlier and that's  
22 significant, correct?

23 **A.** It is the drug family, yes.

24 **Q.** And these thresholds are set per drug family, right?

25 **A.** They are.

1 Q. And where are we at? 9143, do you know what that is  
2 for?

3      **A.**     Since the next column says oxycodone, I know that 9143  
4                          is going to be oxycodone.

5 Q. Yes, sir. Let's see. Then we have the date and month  
6 and the overwrite date. What's the date of this first entry  
7 here?

8      **A.**      8/14/2012.

9 Q. And do you have any knowledge as to whether Cardinal  
10 reported any suspicious orders for Cabell-Huntington prior  
11 to 8/14/2012?

12      **A.**     I have no independent knowledge.

13 Q. If they did, they would be saved in the Cardinal  
14 system, correct?

15      **A.** Not necessarily.

Q. Did Cardinal erase its orders?

17 | A. Not that I'm aware of.

18 Q. Okay. So, if they reported them and it was saved in  
19 their system, then we would have them, right?

20       **A.** I would think so, but I don't know what the record  
21           retention policy of this document would be. You know, I --  
22           I don't know -- I'm not the IT guy, so I don't know what the  
23           IT folks do, how long they keep things, or what have you.

24 MR. FULLER: Your Honor, if I could have one  
25 second, I think I'm --

1                   THE COURT: Yeah.

2 (Pause)

3                   MR. FULLER: Your Honor, I'll pass the witness.

4                   THE COURT: All right. Thank you, Mr. Fuller.

5 Ms. Mainigi?

6                   MS. MAINIGI: Yes, Your Honor.

7                   Mr. Simmons, are we ready to go or do you need a couple  
8 of minutes?

9                   We probably just need a couple of minutes of  
10 transition, Your Honor, if that's okay.

11                  THE COURT: Okay. Let's just -- I'll stay on the  
12 bench.

13                  MS. MAINIGI: Sure.

14                  THE COURT: And you can go ahead and do it that  
15 way.

16                  MS. MAINIGI: Thank you, Your Honor.

17                  MS. MAINIGI: Mr. Simmons, are we ready?

18                  Good afternoon, Mr. Mone.

19                  THE WITNESS: Good afternoon.

20                  Mr. Simmons, let's go ahead and put Demonstrative 2 up.

21                   **CROSS EXAMINATION**

22                   **BY MS. MAINIGI:**

23                  **Q.** I just want to take a few minutes and review your  
24 background before you came to Cardinal, Mr. Mone.

25                  **A.** Okay.

1       **Q.**     Does this demonstrative accurately reflect your  
2 qualifications and background before you came to Cardinal  
3 Health?

4       **A.**     It is a summary of my background, yes.

5       **Q.**     And can you describe for us your educational  
6 background, please?

7       **A.**     So, educationally, I attended the University of  
8 Florida. I graduated from there twice, once from the  
9 College of Pharmacy and once from the College of Law.

10      **Q.**     Could you pull the microphone a little bit closer? I'm  
11 having a little bit of a hard time.

12      **A.**     Okay. Is that -- is that better?

13      **Q.**     Yes. That's wonderful.

14      **A.**     Sorry.

15      **Q.**     Have you worked as a practicing pharmacist?

16      **A.**     I have.

17      **Q.**     And did you also work for the Florida Board of  
18 Pharmacy?

19      **A.**     I did.

20      **Q.**     Can you tell us at high level what you did for the  
21 Florida Board of Pharmacy?

22      **A.**     When I went to work for the Board of Pharmacy, I was a  
23 prosecutor for the Florida Board.

24      **Q.**     And are there particular types of actions you  
25 prosecuted?

1       **A.**     The -- the actions that were found to have probable  
2 cause. So, I would prosecute at the administrative law  
3 level pharmacists and pharmacies over allegations of  
4 deviations from the standard and statutes for the practice  
5 of pharmacy and pharmacists.

6       **Q.**     And did that work give you experience in pharmacy  
7 regulation?

8       **A.**     It did.

9       **Q.**     And then, did you later work for the Florida Attorney  
10 General's Office?

11      **A.**     I did.

12      **Q.**     And describe for us what you did there.

13      **A.**     I served as the General Counsel for Administrative  
14 Regulatory Boards, the Board of Osteopathic Medicine,  
15 Veterinary Medicine, Podiatric Medicine, and I also served  
16 as an Assistant on the Board of Medicine's Probable Cause  
17 Panel.

18      **Q.**     And did you have occasion in that role to address  
19 issues related to opioids and other controlled substances?

20      **A.**     I did as it related to those practitioners who were  
21 licensed in those particular fields.

22      **Q.**     After the Florida AG's office, what was your next role?

23      **A.**     I was -- I was voted, I was elected, I'm not sure what  
24 the right term is. The Kentucky Board of Pharmacy decided  
25 to hire me as their Executive Director.

1 Q. Tell us about that role. What did you do there?

5 Q. Now, in that Executive Director role, did you take any  
6 steps related to the prevention of the misuse of  
7 prescription medications?

8           **A.**       Yes.

9 Q. Can you describe that for us, please?

10       **A.**     Sure. While I was the Executive Director of the Board,  
11                  in conjunction with the Cabinet for Health -- the Cabinet  
12                  for Drug Services, the title I may have messed up, but at  
13                  the instance of the Attorney General, Drug Control and the  
14                  Board of Pharmacy worked on the establishment of the  
15                  Prescription Monitoring Program in Kentucky.

16 Q. And what was the Prescription Monitoring Program that  
17 you worked on?

18       **A.**     It's called KASPER and it was an all-schedule  
19            electronic reporting system that was implemented in  
20            Kentucky.

21 Q. And what was the goal of that Prescription Monitoring  
22 Program?

23       **A.**     The goal of the -- at least as far as I could  
24           determine, the goal of the Prescription Monitoring Program  
25           was to provide a tool so -- to the practitioners, those who

1       wrote prescriptions, as well as those who dispensed  
2       prescriptions, to obtain a more full picture of the  
3       patient's use of controlled substances.

4       **Q.**      And when you say practitioner, are you referring to  
5       prescribers?

6       **A.**      Yes. Practitioners who have the authority to  
7       prescribe, yes.

8       **Q.**      And who had access to this system that you helped with?

9       **A.**      The practitioners, the prescribers, the dispensers,  
10       Drug Control themselves and I'm --

11       **Q.**      Did wholesale -- I'm sorry.

12       **A.**      And I'm sure whoever else was in the statute that said  
13       that they could have it. I just don't recall all the rest  
14       of the folks.

15       **Q.**      Do you recall whether wholesale distributors had access  
16       to this program?

17       **A.**      They did not. The program contains protected health  
18       information and wholesalers do not have access to the  
19       information.

20       **Q.**      Besides the Kentucky Board of Pharmacy, can you  
21       describe other positions that you've held related to  
22       pharmacy?

23       **A.**      Yeah. On the slide, it reflects that I was a member of  
24       the Ohio Board of Pharmacy. I served two terms there as  
25       President of the Board. I suspect you can look at my career

1 and say I tried to spend most of my career in public  
2 service.

3 And then the last bullet there is the National  
4 Association of Boards of Pharmacy where I -- as a -- as the  
5 Executive Director of the Kentucky Board of Pharmacy, I was  
6 elected to the Executive Committee of NEVP, but probably  
7 more significantly for me, is that for more than 20 years, I  
8 have served on the multi -- the Multi-State Pharmacy  
9 Jurisprudence Exam Review Committee.

10 **Q.** And what does that committee do?

11 **A.** It's the committee that puts together the law exam that  
12 every pharmacist in the country takes in order to get a  
13 license to be a pharmacist or to reciprocate from state to  
14 state.

15 **Q.** Thank you, Mr. Mone.

16 MS. MAINIGI: Now, we can go ahead and take that  
17 down, Mr. Simmons.

18 BY MS. MAINIGI:

19 **Q.** You spent some time with Mr. Fuller just setting the  
20 stage in terms of the timetable that you were -- the time  
21 period that you were at Cardinal Health running the  
22 Anti-Diversion System; do you recall that?

23 **A.** I do.

24 **Q.** And I think you told us that Mr. Steve Reardon came  
25 before you in terms of running the Anti-Diversion Program;

1 is that right?

2 | A. It is.

3 Q. And then Mr. Todd Cameron came after you in terms of  
4 running the Anti-Diversion Program at Cardinal, correct?

5           **A.**       He did.

6 Q. So, when you arrived in December, 2007, you said that  
7 the Cardinal Health Anti-Diversion Program was in the  
8 process of changing; do you recall that?

9           | A. I do.

10 Q. What was your understanding of why the Cardinal program  
11 was changing in that time period?

12       **A.**     My understanding of the basis for the change was that  
13           Mr. Reardon had attended a DEA Industry Conference a few  
14           months earlier and came back and began the development of  
15           the electronic -- the electronic component of the Suspicious  
16           Order Monitoring System.

17 Q. Now, what is your understanding of what happened at the  
18 conference?

19       **A.**     My understanding of what happened at the conference was  
20           that a competitor had presented in conjunction with the DEA  
21           and explained their new electronic system for reporting  
22           suspicious orders and that the expectation of the DEA had  
23           changed relative to when Suspicious Order Reports would be  
24           sent to DEA.

25 Q. Was that competitor AmerisourceBergen?

1           **A.**       It was.

2 Q. And do you recall whether that conference was in that  
3 September, 2007 time period right before you arrived?

4       **A.**     Yeah. It was -- it was shortly before, so September is  
5 probably right.

6 Q. And with respect to the DEA expectations that you  
7 understood as you came in and took over the Anti-Diversion  
8 System, you mentioned the electronic system. Were there any  
9 other components that you're recalling got -- that Mr.  
10 Reardon brought back for implementation?

11       **A.**     I call it the three prongs of what we did, which was  
12           Know Your Customer, electronic monitoring and  
13           investigations.

14 Q. Those were the three prongs that Mr. Reardon brought  
15 back?

16       **A.**     To the best of my recollection, that's what were  
17                  brought back.

18 Q. And if I could ask you to bring that a little bit  
19 closer to you. Still having a little bit of difficulty.

**A.** I'm sorry.

21 Q. That's better. Thank you.

Now, when you arrived in December, 2007, Cardinal Health was in the process of building out a system consistent with the new expectations of DEA?

25      **A.**     I would say that's a fair statement.

1       **Q.**   And you were charged with assisting an implementation  
2       of those changes?

3       **A.**   Yes, I was.

4       **Q.**   Now, did you come to understand whether there was any  
5       discussion at the conference about whether suspicious orders  
6       should be shipped?

7       **A.**   I did.

8       **Q.**   And what was your understanding?

9       **A.**   That suspicious orders were not to be shipped to  
10      customers.

11      **Q.**   Did you understand that that expectation was the same  
12      or different than it had been before?

13      **A.**   That it was different.

14      **Q.**   In your understanding, was there a statutory or  
15      regulatory requirement to not ship suspicious orders?

16      **A.**   Given that the statutory reference to suspicious orders  
17      hasn't changed since, from what I could tell back then and  
18      what I understand to be the current language, since the  
19      language itself hasn't changed, it had to be a change in  
20      expectations.

21      **Q.**   A change in expectations by the DEA?

22      **A.**   Correct.

23      **Q.**   Now, after you became the Head of Cardinal Health's  
24      Anti-Diversion Team, did Cardinal Health receive any letters  
25      from the DEA about their new expectations?

1       **A.**     The letter that I recall is the -- and I don't recall  
2                  the specifics of the letter, you know, what -- what is  
3                  essentially in it, but there was a December, 2007 letter  
4                  from Joe Rannazzisi.

5       **Q.**     And so, when you arrived, Cardinal Health began the  
6                  process or continued the process of implementing changes as  
7                  a result of the September, 2007 conference, as well as the  
8                  December Rannazzisi letters?

9       **A.**     Yes.

10      **Q.**     Now, when you arrived, did you also have an opportunity  
11               to assess the system that existed before Cardinal began  
12               making changes post-September, 2007?

13      **A.**     If you're referring the ILR System, yes, I had an  
14               opportunity to assess ILR System.

15      **Q.**     I am. And could you describe for us what an ILR is and  
16               an ILR System?

17      **A.**     My understanding of the ILR System is the Ingredient  
18               Limit Reports, which was an end of the month report to the  
19               DEA of orders.

20      **Q.**     And do you know what Cardinal did with the ILR Reports?

21      **A.**     I do not.

22      **Q.**     Do you know what contact Cardinal had with the DEA or  
23               the Cardinal Health Distribution Centers, what contact they  
24               had with the DEA?

25      **A.**     Well, in that assessment that was done, not only did

1       the distribution centers produce the ILRs and submit them to  
2       DEA, but then, according to the regulation, which went to  
3       the local DEA folks, the -- it was my understanding that the  
4       cage and vault folks and the compliance officers would,  
5       based upon their relationships, pick up the phone, call DEA  
6       and say, hey, here's a suspicious order.

7       **Q.**     So, as you're -- as you understood it, the distribution  
8       centers made calls to the DEA reporting suspicious orders?

9                    MR. FULLER: Your Honor, I'm going to object.

10          One, now counsel is now testifying. And, two, when I asked  
11       Mr. Mone about the earlier system, he had no recollection.

12          MS. MAINIGI: Your Honor, if I may, I don't recall  
13       the specifics, but I believe that he did reference ILRs to  
14       Mr. Fuller in relation to that questioning and I don't  
15       believe Mr. Fuller asked him about distribution centers  
16       making calls to report suspicious orders.

17          MR. ACKERMAN: I also -- I don't think my  
18       microphone is on.

19          THE COURT: Overruled. Go ahead.

20          MS. MAINIGI: Let me just rephrase the question.

21          BY MS. MAINIGI:

22       **Q.**     Mr. Mone, to your understanding as you were assessing  
23       the prior system, did you understand whether Distribution  
24       Centers of Cardinal were making calls to the DEA reporting  
25       suspicious orders?

1           **A.** Yes.

2           **Q.** As part of your assessment of the old system, did you  
3 come to believe that Cardinal Health, that the system it was  
4 running under Mr. Reardon, complied with the Controlled  
5 Substances Act?

6           MR. FULLER: Object to form, Your Honor. I'm  
7 sorry. Not object to form. There's no foundation, Judge.

8           MS. MAINIGI: He assessed the prior system, Your  
9 Honor.

10          MR. ACKERMAN: Also calls for a legal conclusion.

11          THE COURT: Well, I'll sustain the objection.

12          You can rephrase the question, Ms. Mainigi.

13          MS. MAINIGI: Okay. I believe Mr. Fuller did ask  
14 Mr. Mone about his understanding of the Controlled  
15 Substances Act.

16           BY MS. MAINIGI:

17          **Q.** So, Mr. Mone, do you recall talking to Mr. Fuller about  
18 your understanding of the Controlled Substances Act?

19          **A.** I do.

20          **Q.** And the Controlled Substances Act is an act that you  
21 became quite familiar with in your role as Head of  
22 Anti-Diversion; is that right?

23          **A.** I did.

24          **Q.** And did you review with us, I think earlier, the  
25 different components of what was required of Cardinal under

1                   the Controlled Substances Act?

2         **A.**    To the best of my recollection, we were earlier talking  
3                   about the statutory component of maintaining effective  
4                   controls against diversion and the regulatory component,  
5                   which was to develop a system to identify and report  
6                   suspicious orders.

7         **Q.**    In your assessment of the prior system did you come to  
8                   believe that Cardinal Health's prior system operated  
9                   consistent with the Controlled Substances Act?

10                  MR. FULLER: Same objection, Judge. This witness  
11                   had no knowledge of the prior system when I asked him.

12                  MS. MAINIGI: I don't think that's correct, Your  
13                   Honor.

14                  THE COURT: Well, overruled. I think he -- he did  
15                   testify about that, at least that he had knowledge of it.

16                  BY MS. MAINIGI:

17         **Q.**    Do you need the question again, Mr. Mone?

18         **A.**    Yes, please.

19         **Q.**    When you assessed the prior Cardinal Health system, did  
20                   you form an understanding as to whether the prior system  
21                   that Cardinal Health had, whether that was operating  
22                   consistent with the Controlled Substances Act?

23         **A.**    It would seem to -- the answer is yes. It would seem  
24                   to me that if a distributor were providing an ILR to the DEA  
25                   for all the years that they were doing it and the regulation

1 never changed, it had to be in compliance.

2 MR. ACKERMAN: Your Honor, I object on the ground  
3 that I --

4 THE COURT: One lawyer.

5 MR. ACKERMAN: I'm objecting for the City of  
6 Huntington, Your Honor.

7 THE COURT: Oh, okay. I'm sorry, Mr. Ackerman.

8 MR. ACKERMAN: Yes. We've switched now, so my  
9 microphone is back on. Object to that -- I think the  
10 witness's answer stated a legal conclusion. The question  
11 was a yes or no question, but the -- but in explaining the  
12 answer, the witness stated a legal conclusion. So, I'd  
13 object on that ground and move to strike.

14 THE COURT: Well, it's his understanding of what  
15 the situation requires. I'm going to overrule that and let  
16 him answer.

17 BY MS. MAINIGI:

18 Q. Now, let me -- we'll cover some changes, Mr. Mone,  
19 specific changes that you made going forward, but let me ask  
20 you, besides the changes that got made at the end of 2007,  
21 beginning of 2008, while you were Head of Anti-Diversion,  
22 was this the only time that Cardinal Health made changes to  
23 its system?

24 A. No. We were engaged in a continuous improvement  
25 process the entire time I was there.

1           **Q.** Now, do you recall Mr. Fuller asking you some questions  
2 about this 2008 settlement with the DEA?

3           **A.** I -- I vaguely recall them, yes.

4                         MS. MAINIGI: Your Honor, as you know, we have  
5 objected to a discussion of that based on geographic scope  
6 and we retain our objection to that, but I am going to ask a  
7 few questions since Mr. Fuller was allowed to ask questions  
8 and we don't waive --

9                         THE COURT: You may ask questions without waiving  
10 the objection.

11                         MS. MAINIGI: Yes, Your Honor. Thank you.

12                         THE COURT: That's fine. The objection will be  
13 preserved.

14                         BY MS. MAINIGI:

15           **Q.** Around the same time that you took your position at  
16 Anti-Diversion at the end of 2007, did the DEA begin  
17 enforcement actions related to certain Cardinal Health  
18 Distribution Centers?

19           **A.** Yes.

20           **Q.** Now, in terms of timeline, if I represent to you that  
21 the ABDC Conference was September 2007, do you recall when  
22 the first immediate suspension order against a Cardinal  
23 Health Distribution Center occurred?

24                         MR. FULLER: Objection, foundation, Judge.

25                         THE COURT: Overruled. If he remembers, he can

1 answer.

2 THE WITNESS: To the best of my recollection, it  
3 was -- it was towards the end of November of 2007.

4 BY MS. MAINIGI:

5 Q. And was that the Auburn-Washington State facility?

6 A. Auburn was the first one, yes.

7 Q. And then were there two more in December, the month  
8 that you arrived?

9 A. Yes.

10 Q. And were those Lakeland, Florida and Swedesboro, New  
11 Jersey?

12 A. Yes. Swedesboro on my 50th birthday.

13 Q. Happy birthday.

14 A. Thank you.

15 Q. Was there also an Order to Show Cause in January, 2008?

16 A. I do not recall whether it was December or January, but  
17 I do recall an Order to Show Cause.

18 Q. And do you recall that was Stafford, Texas?

19 A. It was Texas.

20 Q. And each of those four distribution centers, Mr. Mone,  
21 had a separate registration with the DEA; is that correct?

22 A. They did, yes.

23 Q. And do you recall generally what type of pharmacies  
24 were involved in the 2008 DEA action?

25 A. They were predominantly what in the literature and the

1           DEA language were called internet pharmacies.

2       **Q.**    To your recollection by this point in time, had  
3           Cardinal Health taken measures to ensure that none of its  
4           customers were acting as internet pharmacies?

5       **A.**    Yes.

6       **Q.**    Now, do you recall around that time how many  
7           distribution centers Cardinal Health had approximately?

8       **A.**    I know that there were more than 20. I don't recall  
9           the specific number.

10      **Q.**    And do you recall any allegation in this point in time,  
11           the end of 2007, beginning of 2008, against the Wheeling,  
12           West Virginia Cardinal Health Distribution Center?

13      **A.**    No. I don't believe there was anything ever about  
14           Wheeling.

15      **Q.**    And, to your knowledge, did any of the distribution  
16           centers at issue in the 2008 enforcement actions ship  
17           controlled substances to West Virginia?

18      **A.**    To pharmacies in West Virginia?

19      **Q.**    Correct.

20      **A.**    No.

21      **Q.**    And I think you've already testified that by the time  
22           you got some of these enforcement actions, Cardinal Health  
23           had already begun to make changes to its Suspicious Order  
24           Monitoring System?

25      **A.**    Yes, it had.

1 Q. Did Cardinal Health ultimately reach a settlement with  
2 the DEA?

3      **A.**      It did.

4 Q. And was that in the 2008 time period?

5      **A.**    To the best of my recollection, yes.

6 Q. And did the four distribution centers at issue regain  
7 their DEA registrations as part of that process?

8           **A.**     They did.

9 Q. To your knowledge, in the 2008 DEA settlement, was  
10 there any admission of liability or finding of wrongdoing by  
11 Cardinal Health?

**A.** To the best of my knowledge, there was none.

13 Q. And as part of the settlement with the DEA did Cardinal  
14 Health agree that its Suspicious Order Monitoring Program  
15 would not ship suspicious orders and would report those  
16 orders to the DEA?

17       **A.**     And -- yes, and it would report those orders to the DEA  
18                  in Washington.

19 Q. As opposed to the Field Offices?

20      A.      Correct.

21 Q. And was this agreement that was in the 2008 settlement,  
22 was that consistent with the updated DEA guidance that had  
23 been provided in the September, 2007 conference, as well as  
24 the December 2007 Rannazzisi letter?

25 A. I believe the answer to that is yes.

1       **Q.** To your knowledge, did Cardinal Health meet all the  
2 terms and conditions of the Settlement Agreement?

3       **A.** Oh, yes.

4       **Q.** Now, we've walked through your qualifications. Let's  
5 put up an organizational chart so we can talk about  
6 anti-diversion at Cardinal Health.

7                  MS. MAINIGI: Demonstrative 3, please, Mr.  
8 Simmons.

9                  MR. ACKERMAN: Could I get a copy of this, please?

10                 MR. FULLER: Can I be shown a copy before?

11                 MS. MAINIGI: Sure. Let's take it down.

12                 MR. ACKERMAN: And, Your Honor, I just want to --  
13 I just want to make this point more globally. I think there  
14 was discussion earlier about not showing demonstratives  
15 until the other party has had an opportunity to review it  
16 and object. We haven't received any copies of  
17 demonstratives, so we, I think, should have that same  
18 opportunity.

19                 THE COURT: Okay.

20                 MS. MAINIGI: Your Honor, I believe we addressed  
21 this issue when it came up with the corporate witnesses for  
22 ABDC, but there was not an agreement to share demonstratives  
23 in advance in -- as it relates to our demonstratives.

24                 MR. ACKERMAN: Well, Your Honor, the defendants  
25 certainly made that request of us. I can't imagine it would

1       be the case that we would be required to show them and not  
2       the defendants.

3                  THE COURT: Well, I don't see any harm in putting  
4       it up since there's no jury here before -- I remember the  
5       discussion this morning and everything, but --

6                  MR. ACKERMAN: I just want to make sure, Your  
7       Honor, that the same rules apply to us apply to the  
8       defendants when they present their case through a witness.  
9       That's our concern.

10                 THE COURT: Okay.

11                 MS. MAINIGI: Your Honor, we're happy to discuss.

12                 THE COURT: Yes. Don't put it up until Mr.  
13       Ackerman has had a chance to look at it.

14                 MS. MAINIGI: Okay. That's fine, Your Honor.

15                 MR. ACKERMAN: Mr. Fuller says it's fine. I will  
16       -- I will go along with him on this one.

17                 MS. MAINIGI: Mr. Fuller?

18                 MR. FULLER: Sure, Judge. It's fine.

19                 MS. MAINIGI: Thank you, Mr. Fuller.

20                 BY MS. MAINIGI:

21       **Q.** This is an organizational chart related to Cardinal  
22       Health. Mr. Mone, in the 2008 to 2012 time period, does  
23       this org chart accurately reflect the folks that were above  
24       you and below you?

25       **A.** The positions do. The names are not necessarily a

1                   correct reflection.

2       **Q.**    I think you told us earlier that, at some point, Mark  
3                   Hartman became Gilberto Quintero?

4       **A.**    That is correct, yes.

5       **Q.**    Okay. And that role, the Mark Hartman/Gilberto  
6                   Quintero role, can you tell us about that role?

7       **A.**    That's my boss -- or shouldn't make it present tense.  
8                   That was my boss.

9       **Q.**    And that role over -- can you describe what that role,  
10                  the Mark Hartman role, oversaw?

11      **A.**    Yeah. That role was responsible for QRA Operations and  
12                  involved the RPs, the Anti-Diversion piece, and then Steve  
13                  Reardon's piece, which was the Quality and Regulatory  
14                  Affairs piece that related to the rest of the obligations  
15                  with regard to the distribution centers.

16      **Q.**    Now, when you -- so, Mr. Reardon had your role before  
17                  you came in, correct?

18      **A.**    Correct. It was combined, one role under Steve.

19      **Q.**    And then the role got split off into two; is that  
20                  right?

21      **A.**    Yes. I came along and I picked up the anti-diversion  
22                  piece.

23      **Q.**    And so, the piece that Mr. Reardon held onto, can you  
24                  just give us a little bit more description of what that role  
25                  entailed?

1       **A.**     Sure. He held onto the compliance officers, which is  
2 why you see only a dotted line to me. They actually are --  
3 they're actually a solid line in to Steve.

4       **Q.**     And you meant -- I'm sorry. Go ahead.

5       **A.**     And Steve handled the Distribution Center licensing and  
6 security and the other components of the Distribution  
7 Center.

8       **Q.**     So, what do the compliance officers do at the  
9 distribution centers?

10      **A.**     Well, they're -- a lot of things. They're responsible  
11 for the cage and vault. They're responsible for licensing.  
12 They're responsible for maintaining the on-site records.  
13 They're responsible for communicating to -- to  
14 anti-diversion. And they're responsible to communicate up  
15 to Steve.

16      **Q.**     Now, I see underneath you is Know Your Customer and I  
17 know that's a component of the system going forward, but can  
18 you describe why it's on the org chart?

19      **A.**     Yeah. We -- what we did was, you know, as I indicated  
20 before, any good system is a PPT, people, process, and  
21 technology. And so, we took the components of the system,  
22 grouped individuals into areas of excellence, and placed  
23 them in the system so that the Know Your Customer folks or  
24 the intake folks, the Know Your Customer analyst folks that  
25 worked with the pharmacists.

1 Q. So did -- did the Know Your Customer folks evaluate and  
2 conduct diligence on new customers?

3           **A.**     They did.

4 Q. And also existing customers?

5           **A.**     They did.

6 Q. And were there -- there were questionnaires associated  
7 with that process? Did they fill those questionnaires out?

8       **A.**   They did not fill the questionnaires out.

9                           MR. ACKERMAN: Your Honor, a leading objection to  
10                          the last question.

11 MS. MAINIGI: I'm just trying to move this along,  
12 Your Honor.

16 THE WITNESS: The answer is they didn't fill it  
17 out. The customers filled it out.

18 BY MS. MAINIGI:

19 Q. What did the Know Your Customer folks do with the  
20 questionnaires?

21       **A.** They took it and where there -- as I indicated to  
22       counsel this morning, where there were objective ways of  
23       assessing what the customer provided, they would look those  
24       up, you know, licensure, and make sure that the licensure  
25       was right, and the objective data that they could find, and

1       then they would pass that on to the pharmacist.

2       **Q.**     Then there is electronic order monitoring and  
3           pharmacists. And I know you referred several time to  
4           pharmacists with Mr. Fuller. Can you describe the role of  
5           those individuals?

6       **A.**     These pharmacists were, as Mr. Fuller and I had the  
7           unfortunate discussion about pharmacists being -- these are  
8           our pharmacists who were assessing -- were doing the  
9           assessment of both the data that was provided through the  
10          Know Your Customer piece, as well as doing the evaluation of  
11          the threshold events.

12       **Q.**     And then there's an Investigations Team. What did they  
13          do?

14       **A.**     When the pharmacist made a request for additional  
15          information, the pharmacist would send it over to the  
16          Investigatory Team, who would then do a site visit -- to do  
17          a site visit of the pharmacy and those -- the boxes are our  
18          folks and we had additional -- and we talked about it  
19          earlier. We had the additional consultants that would go  
20          out and do those inspections.

21       **Q.**     And then the Analytics Team, what did the Analytics  
22          Team do?

23       **A.**     The Analytics Team was the team that produced the data  
24          that Mr. Fuller provided to me earlier and would work with  
25          the IT Team to -- to build the analytics capability.

1       **Q.**   Now, as a wholesale distributor, is it fair to say  
2           Cardinal Health supplies a lot of products beyond opioids to  
3           its customers?

4       **A.**   Yes. We're a full -- full line -- Cardinal Health is a  
5           full line pharmaceutical wholesale distributor.

6       **Q.**   What are the other types of products at a very high  
7           level that Cardinal Health provides?

8       **A.**   Very high level, your asthma inhalers. You know, your  
9           hospital supplies we provide from -- oh, from Band-Aids to  
10          specialty medications in the distribution channel.

11       **Q.**   As a wholesale distributor, does Cardinal Health  
12          develop opioids?

13       **A.**   It does not. It is not a manufacturer.

14       **Q.**   Does it seek approval from the FDA to market opioids?

15       **A.**   It does not.

16       **Q.**   Does Cardinal Health develop or conduct clinical tests  
17          on the risks and benefits of opioids?

18                   MR. FULLER: Object to form. Foundation.

19                   THE COURT: Overruled.

20                   THE WITNESS: To the best of my knowledge, we  
21          don't have any clinical folks that do that.

22                   BY MS. MAINIGI:

23       **Q.**   We've talked about the Closed System of Distribution.  
24          Can you describe what the Closed System of Distribution  
25          means?

1       **A.**     The Closed System of Distribution is the process by  
2 which everyone in the supply chain --

3       **Q.**     Actually, hold that thought. Let me get another  
4 demonstrative and let me show Mr. Fuller.

5                 Mr. Simmons, if you could put up Demonstrative 4,  
6 please.

7                     THE WITNESS: That's the -- that.

8                     BY MS. MAINIGI:

9       **Q.**     Is this a picture of the Closed System of Distribution?

10      **A.**     Yeah. It represents the individuals who are registered  
11 by -- the closest in the distribution is everybody that's  
12 registered by the Drug Enforcement Administration. So, when  
13 product moves between all of these entities or that the --  
14 every one of those folks is -- has a DEA registration, the  
15 folks that are outside of the patients.

16      **Q.**     So, to prescribe opioids, do prescribers have to be  
17 registered with the DEA?

18      **A.**     Yes, they do. And any -- you know, any controlled  
19 substance that they wish to prescribe, they have to be  
20 registered with the DEA.

21      **Q.**     And the pharmacy, if it's going to dispense opioids,  
22 has to be registered with the DEA?

23      **A.**     In order to possess and dispense them, they, too, have  
24 to be registered with the DEA.

25      **Q.**     Now, you described something earlier, you mentioned it

1       a few times with Mr. Fuller, corresponding responsibility.

2       Define that for me.

3       **A.**     Well, the corresponding responsibility is a term in the  
4       regulations of the -- of the DEA, the CFR, that relates to  
5       the --

6                  COURT REPORTER: Can you keep your voice up just a  
7       little bit for me, please?

8                  THE WITNESS: Sure.

9                  COURT REPORTER: Thank you.

10                 THE WITNESS: Hold on a second. Let's --

11                 MS. MAINIGI: Maybe -- I don't know if that  
12       microphone pulls a little bit closer.

13                 THE WITNESS: I'm almost off the desk, but --

14                 MS. MAINIGI: Okay, sorry.

15                 THE WITNESS: And the chair doesn't move. The  
16       chair doesn't move, so I'm -- so, the only thing I can do  
17       for you is to raise my voice and I'll do that.

18                 MS. MAINIGI: Thank you.

19                 THE WITNESS: The corresponding responsibility is  
20       the -- is a component of the regulations for DEA as it  
21       relates to pharmacists that reflects that the pharmacists,  
22       in their determination to dispense a controlled substance,  
23       must undertake a corresponding responsibility to essentially  
24       assess whether the doctor who has that primary obligation,  
25       when they make the decision to prescribe, has written the

1           prescription in good faith in the course of professional  
2           practice for a legitimate medical purpose.

3                         BY MS. MAINIGI:

4           **Q.**    And that's the pharmacist's responsibility?

5           **A.**    That's a corresponding responsibility, yeah.

6           **Q.**    Now, what is the Cardinal role at a high level in this  
7           Closed System?

8           **A.**    In this Closed System, the high level is we buy -- only  
9           to the extent that we're talking about controlled  
10          substances.

11          **Q.**    Yes. Let's go through some of that.

12          **A.**    It purchases controlled substances from a DEA  
13          registered manufacturer, has a DEA registration to hold it,  
14          to possess it, and enables it to sell that controlled  
15          substance to another DEA registered entity.

16          **Q.**    In the closed system, does a Cardinal Health ship  
17          directly to patients?

18          **A.**    No. There's no relationship to the patient.

19          **Q.**    When Cardinal ships medication to a pharmacy, how does  
20          the medication go from the pharmacy's shelves to the  
21          patients?

22          **A.**    Presumptively, the pharmacist receives a prescription  
23          that they make an assessment of that, the physician wrote it  
24          in good faith in the course of professional practice and for  
25          a legitimate medical purpose, thereby assuring themselves,

1 meeting their corresponding responsibility, and then  
2 prepares it and dispenses it to the patient.

3 **Q.** So, if no patient comes in with a prescription to a  
4 pharmacy, what happens to the medication that the pharmacy  
5 ordered from Cardinal Health?

6 **A.** It sits on the shelf.

7 **Q.** And does that apply to all medications or just  
8 controlled substances?

9 **A.** Everything. You know, any legend drug, any -- let me  
10 -- I don't want to have definitions of legend drugs. Any  
11 prescription item first requires the patient to present a  
12 valid prescription to the pharmacist.

13 **Q.** Now, within this Closed System were quotas set by DEA  
14 as to the nationwide amount of opioids that could be  
15 produced?

16 **A.** Yes. And that applies to the manufacturer of the  
17 product, the quotas.

18 **Q.** And, to your knowledge, did Cardinal Health ever ship  
19 in excess of the DEA quotas?

20 **A.** It would be impossible for Cardinal Health to ship in  
21 excess of the quota.

22 **Q.** Why is that?

23 **A.** Well, because Cardinal Health is not -- first of all,  
24 the easy answer is Cardinal Health is not the only  
25 distributor. And there are no dosage -- there are no

1 amounts above what the DEA quota is that can be  
2 manufactured, so no one could distribute more than what the  
3 quota was.

4 **Q.** To your knowledge, did Cardinal Health ever ship to a  
5 pharmacy in Cabell or Huntington that was not registered  
6 with the DEA and licensed by the State of West Virginia?

7 **A.** To the best of my knowledge, we would not ship to any  
8 customer that was not registered by the State or the -- in  
9 the jurisdictions where the state required controlled  
10 substance registration and a DEA registration.

11 **Q.** And, to your knowledge, did Cardinal Health ever ship  
12 prescription opioids to a pharmacy in Cabell or Huntington  
13 that Cardinal Health knew or should have known was  
14 dispensing for a purpose other than to fill legitimate  
15 prescriptions written by doctors?

16 **A.** No.

17 **Q.** Now, when it comes to some of the reporting that  
18 Cardinal Health does to the DEA, is there reporting called  
19 ARCOS that you're familiar with?

20 **A.** Yes.

21 **Q.** Can you describe what that is?

22 **A.** Well, firstly, that -- the ARCOS reporting vault fell  
23 under Steve.

24 **Q.** Steve Reardon?

25 **A.** Steve Reardon, yeah. He's not there anymore, but Steve

1 Reardon. That's the component of that security and what  
2 have you that Steve did on the QRA side.

3 But the ARCOS Report is a report that is required to be  
4 submitted by -- I think it's manufacturers and distributors  
5 for all schedule Is, all Schedule IIs, and narcotic IIIs.

6 **Q.** So, for every single pill, Mr. Mone, the controlled  
7 substance that Cardinal Health shipped, did the DEA know who  
8 it shipped to?

9 **A.** Ultimately, DEA would know -- be able to know that  
10 information. It directly gets every month the ARCOS Reports  
11 which would -- now, mind you, we don't have any Schedule Is,  
12 but it's all Schedule IIs and Narcotic IIIs.

13 **Q.** And would the DEA know when that shipment occurred?

14 **A.** Yes.

15 **Q.** At any point during your time with Cardinal Health's  
16 Anti-Diversion Team from 2008 to 2012 did DEA inform  
17 Cardinal Health that it believed its shipments to Cabell  
18 County or Huntington were excessive?

19 **A.** No. There was no communication from DEA with regard to  
20 that.

21 **Q.** At any point during your time with Cardinal Health's  
22 Anti-Diversion Team from 2008 to 2012 did DEA inform  
23 Cardinal Health that its shipments to any particular  
24 pharmacy in Cabell County or Huntington were excessive?

25 **A.** No, they did not.

1                   MS. MAINIGI: Your Honor, I'm about to change  
2 sections. Would now be a good time for our break?

3                   THE COURT: Yes. Let's take about a ten-minute  
4 break here.

5                   (Recess taken)

6                   (Proceedings resumed at 3:40 p.m.)

7                   THE COURT: Mr. Mone, you can come on back up,  
8 sir.

9 BY MS. MAINIGI:

10                  **Q.** Welcome back, Mr. Mone.

11                  **A.** Thank you.

12                  **Q.** During the time that you worked at Cardinal, were you  
13 provided the resources necessary for the Anti-Diversion work  
14 that you led?

15                  **A.** Yes.

16                  **Q.** And during your tenure did the Anti-Diversion staff  
17 grow?

18                  **A.** It did.

19                  **Q.** Let's walk through the main components of the  
20 Suspicious Order Monitoring System that you helped to design  
21 and lead.

22                   Demonstrative 5, Mr. Simmons, which counsel has no  
23 objection to, Your Honor.

24 BY MS. MAINIGI:

25                  **Q.** So let's start with the Know Your Customer

1 component. I think you've talked about that a bit with  
2 Mr. Fuller, but did that part of the system involve  
3 gathering information about new customers?

4 **A.** It did.

5 **Q.** And, and how did that work? Describe it to us at a  
6 high level.

7 **A.** Well, the customer process was a holistic process that  
8 involved all of the Cardinal Health team members. It  
9 involved the sales folks that were at the, that were at the  
10 customer. It involved merchandisers. It involved the, the  
11 questionnaire. It involved the assessment of the answers on  
12 the questionnaire. The compliance officers could on  
13 occasion, and would on occasion, go to do ride-alongs with  
14 the, the folks. So we built a program that was, you know,  
15 holistic.

16 **Q.** And what did you do with the information that got  
17 gathered as part of Know Your Customer?

18 **A.** Well, in the initial stages, it was paper and we kept  
19 that paper and it was used by the pharmacists in their  
20 evaluations.

21 **Q.** Now, after a new customer was on-boarded, did the Know  
22 Your Customer process continue?

23 **A.** It did. It was a continuous -- you know, customers  
24 changed. Things changed with regard to the business. So it  
25 was a continuous process.

1       **Q.**     The second component of the system, Electronic Order  
2     Monitoring, can you describe that part of the system,  
3     please?

4       **A.**     Well, that was the technology component of the system  
5     whereby the, the system -- there's a warehouse management  
6     system which -- there's a warehouse management system  
7     that -- in which the orders are placed. And as a module on  
8     top of and alongside it, there was the Electronic Order  
9     Monitoring component that reviewed those orders that came  
10    in.

11      **Q.**     And this is where the thresholds are that you spoke to  
12    Mr. Fuller about?

13      **A.**     Yes.

14      **Q.**     And can you describe -- I know it's a very elaborate  
15    process in terms of setting the thresholds, but at a high  
16    level can you describe the threshold process?

17      **A.**     Yeah. The threshold process was a process whereby we  
18    took the totality of the circumstances that we knew and the  
19    characteristics of the pharmacy and the description of the  
20    patients that they treated, put, put that into a -- put that  
21    into the thought, put that into the thought process and made  
22    an evaluation of the type of customer that they were,  
23    segmenting the classification that they were, whether they  
24    were a retail pharmacy or a hospital or a chain pharmacy,  
25    and then sub sub-setting them into sizes.

1 Q. So were there individualized thresholds for each  
2 pharmacy customer?

8 Q. And what would the categories of information that went  
9 into or were considered in setting a threshold?

10       **A.** Well, we looked at their prior, prior history if it was  
11       available. We looked at the characteristics of the pharmacy  
12       because like a Hospice pharmacy is going to look totally  
13       different than a psych pharmacy which is going to look  
14       totally different than a compounding pharmacy.

15 And they all may be retail independents, but their  
16 individual characteristics are going to differ in terms of  
17 how they are likely to order controlled substances, as well  
18 as every other drug.

19 Q. And over the years that you were there, did you modify  
20 or enhance your threshold setting methodology?

21       **A.** Yes. Over time we consistently looked at and built  
22 models to run the data against to adjust to be as precise as  
23 we could be given the limited information that we had.

24 Q. So if an order went above the threshold that was set  
25 for that particular pharmacy, what would happen next?

1       **A.** Well, the, the order would be held and the pharmacist  
2 would conduct an evaluation.

3       **Q.** Mr. Simmons, could we go back to the chart for a  
4 moment.

5           So the pharmacist in the Electronic Order Monitoring,  
6 those pharmacists would review the order then?

7       **A.** That is correct.

8       **Q.** And what -- to your knowledge, what are some of the  
9 things that that pharmacist or pharmacist team would do at  
10 that stage when an order had kicked to them?

11      **A.** Well, among other things -- and I can't tell you  
12 exactly what each pharmacist would do because there's a,  
13 there's a professional analysis that goes along with it.

14           But they would look at the Know Your Customer  
15 information that they had available to them. They'd look at  
16 the data that they had available to them in the system.  
17 They would look at the order. They would look at where the  
18 pharmacy is located.

19           They would look at -- they would look at, you know,  
20 things like their relationship to a hospital, the customer,  
21 where they were. It's the totality of the circumstances  
22 for, for that pharmacy.

23           Whatever we had and whatever they thought we needed, if  
24 they needed something else, they'd go to the Know Your  
25 Customer folks or they'd pick up the phone and call the

1                   pharmacy, or they would try and get the information that was  
2                   necessary to, to make an appropriate assessment.

3                   **Q.**     Mr. Simmons, could you put the other back up.

4                   Now, when the pharmacist had, had an order that had  
5                   kicked over to them, could their evaluation sometimes  
6                   involve a visit to the pharmacy?

7                   **A.**     Yes.

8                   **Q.**     And could you describe that to me?

9                   **A.**     Well, a visit to the pharmacy would be a, a -- the  
10                  investigative -- it's interesting. I'm going to say this.  
11                  The investigative folks were the primary folks that were  
12                  responsible for doing the investigations, plus the  
13                  consultants that were investigators. And most of those were  
14                  former DEA diversion investigators that we used.

15                  Those folks would go in and they would use the  
16                  framework of the Know Your Customer questionnaire as a basis  
17                  for their inquiry when they got to the pharmacy.

18                  So they did this like -- they, they did a pre-review of  
19                  the data. And they would look at everything that we had.  
20                  They would fill out a pre-review. And then the investigator  
21                  would go in and get information to support or to support and  
22                  affirm the information that they had, or if something had  
23                  changed like, for example, they bought the files and -- you  
24                  know, a chain pharmacy bought a file of a pharmacy that a  
25                  pharmacy had closed, oh, there's, there's a change, and the

1 independent pharmacy bought the files of the pharmacy that  
2 closed, there's a change. How many prescriptions did you  
3 buy, what type of patients, all of that would go into it and  
4 then they would write a report.

5 **Q.** And, so, site visits may kick out of the electronic  
6 order monitoring process, but they might also be part of the  
7 investigations process?

8 **A.** Yeah, yeah. They, they weren't required to be done  
9 that way, you know. But both ways could result in, in, in  
10 an investigation.

11 **Q.** Now, who were the people who would conduct the site  
12 visit?

13 **A.** Well, when, when I got there, I'm a firm believer in  
14 cross functionality of folks. So the investigators that we  
15 hired -- we hired former police. We hired former -- we  
16 hired former Board of Pharmacy inspectors. We hired former  
17 Medicaid fraud unit inspectors. And that was the type of  
18 individual that I wanted, but I wanted a broad swath of them  
19 so that they could cross-train each other.

20 **Q.** And, so, those were some of the types of folks you  
21 hired as investigators who visited the pharmacy?

22 **A.** Yes.

23 **Q.** And the site visit process, was there a checklist or  
24 something that they worked off of?

25 **A.** Like I said, they used the Know Your Customer

1 questionnaire as -- used the Know Your Customer  
2 questionnaire as a framework. They did have their own  
3 document, but that's the framework that they used.

4 **Q.** Now, did you personally ever conduct site visits?

5 **A.** I did on occasion, rare occasions, but I did.

6 **Q.** Now, we've talked a lot about suspicious orders. At  
7 what point does a pharmacist in the Anti-Diversion group  
8 decide whether an order is suspicious?

9 **A.** They would decide that at the end of the evaluation  
10 that they made about the totality of the circumstances for  
11 that pharmacy and that order.

12 **Q.** And when a pharmacist made a determination that an  
13 order was suspicious, what did Cardinal Health do next?

14 **A.** The order was reported to DEA.

15 **Q.** Was it shipped?

16 **A.** No.

17 **Q.** To your knowledge, during your time at Cardinal Health,  
18 did the company ever ship a suspicious order?

19 **A.** No, it did not.

20 **Q.** I'm going to show you briefly a document that was  
21 previously admitted, Mr. Mone, and I don't think you've  
22 necessarily seen it, but I just want to ask you a couple of  
23 questions off of it.

24 Defendants' 1.

25 MR. FULLER: Judge, I would object to the

1 broadcasting until the witness has laid a foundation for it.

2 THE COURT: Okay.

3 MS. MAINIGI: It's an admitted document, Your  
4 Honor.

5 THE COURT: It's already been admitted, Mr.  
6 Fuller. Put it back up.

7 BY MS. MAINIGI:

8 Q. Now, Mr. Mone, what I'm putting in front of you is  
9 Defendants' Exhibit 1 which I will submit to you is the  
10 presentation that was provided at the September 11th,  
11 2007, DEA conference by AmerisourceBergen. And I know  
12 you did not see this presentation at the time. I know  
13 you didn't attend the conference. I know Mr. Reardon  
14 did.

15 There are just a couple of components of the program  
16 that were put forward in this conference that I just want  
17 you to look at and comment as to whether they compare to the  
18 Cardinal system that you helped put together.

19 MR. FULLER: Judge, I'm going to object. She's  
20 going to question a witness who hasn't seen a document that  
21 you've prevented me from doing repeatedly about whatever is  
22 in the document?

23 MR. ACKERMAN: At a conference where the witness  
24 did not attend.

25 MS. MAINIGI: Your Honor, he, he's testified that

1       Cardinal modeled their system from this conference. Others  
2       did attend it and he's the primary architect of the new  
3       system at Cardinal.

4           I've represented that he has not seen the document  
5       before. I just want to walk through some of the generic  
6       components in the document.

7           MR. ACKERMAN: We maintain our foundation  
8       objection, Your Honor.

9           THE COURT: I'll sustain the objection.

10          MS. MAINIGI: We can take that down, Your Honor.  
11        Is it all right if I just run through a few of the  
12       components orally?

13          THE COURT: You can ask the questions and see  
14       where we go.

15          MS. MAINIGI: Okay. That's fine, Your Honor.  
16       BY MS. MAINIGI:

17       **Q.** You can set aside, Mr. Mone, the document. I'm  
18       looking at Page 6 of the document. You described to us  
19       a Know Your Customer component just now to the Cardinal  
20       system; correct?

21       **A.** I did.

22       **Q.** And you also described an Order Monitoring Program type  
23       component and Electronic Monitoring Program component?

24       **A.** Yes.

25       **Q.** And did you describe to me an investigations component?

1       **A.**   I did.

2       **Q.**   And was there training also done at Cardinal Health  
3                  related to Anti-Diversion?

4       **A.**   Yes.

5       **Q.**   Can you describe that for me at a high level?

6       **A.**   At a high level we built modules, training modules that  
7                  were a component of performance metrics for employees that  
8                  involved reviewing the presentation and taking a test and  
9                  requiring you to get 100 percent on the test before you  
10                 could -- otherwise, you would be in this constant loop of  
11                 watching the slides again until you got 100 percent of the  
12                 answers correct.

13      **Q.**   Who -- let me back up. Who received training on  
14                  Anti-Diversion at Cardinal Health?

15      **A.**   Well, to the best of my knowledge, I'm going to say  
16                  just about everybody. What we did was -- Anti-Diversion was  
17                 everybody's -- was everyone's responsibility. And the folks  
18                 that I know that did were the, the sales folks, the sales op  
19                 folks, my folks, and the distribution center employees. I  
20                 know those folks did.

21      **Q.**   And you were describing this 100 percent -- everybody  
22                 had to take a test and get 100 percent on the test; is that  
23                 right?

24      **A.**   You got the question wrong, you went back through the  
25                 slides again. And I think the testing folks were even mean

1 because when you got to the questions, they rearranged the  
2 answers so that you couldn't memorize that the answer was,  
3 the one you put was C and, you know, they were just sneaky.

4 **Q.** Okay. Now, your Know Your Customer due diligence, did  
5 Cardinal Health's program for Know Your Customer also  
6 include a new account set-up process, the new account  
7 questionnaires?

8 **A.** It did.

9 **Q.** And you discussed already the on-site visit. Is that  
10 fair?

11 **A.** Yes.

12 **Q.** Monthly sales limits. Did Cardinal Health have monthly  
13 sales limits for its customers?

14 **A.** I don't know what you mean by sales limits.

15 **Q.** Did Cardinal's system segment customers by size  
16 initially?

17 **A.** Yes, it did.

18 **Q.** And Cardinal Health called those thresholds?

19 **A.** Yes.

20 **Q.** During the time you were head of Anti-Diversion at  
21 Cardinal Health, did the Wheeling distribution center have a  
22 DEA registration that entire time?

23 **A.** It did.

24 **Q.** And in that time period, 2007 to 2012, did distribution  
25 centers have to periodically renew their DEA registration?

1       **A.**     They -- they're required to periodically renew. I  
2                   think it's a three-year license.

3       **Q.**     So, to your knowledge, did DEA renew the Wheeling, West  
4                   Virginia, distribution center license each time it applied?

5       **A.**     I would submit to you that it did.

6       **Q.**     Is it your understanding that if the DEA had ever had a  
7                   problem with the Wheeling facility that they would have let  
8                   you know about it?

9       **A.**     I would like to believe that they would have.

10      **Q.**     Is it fair to say that if the DEA had an issue with  
11                   Cabell/Huntington pharmacies, they would have done something  
12                   about it to your understanding?

13                   MR. ACKERMAN: Objection, speculating.

14                   THE COURT: Well, if he knows.

15                   THE WITNESS: I, I would like to believe they  
16                   would inform me.

17                   BY MS. MAINIGI:

18      **Q.**     To receive and maintain a DEA registration, did DEA  
19                   have to determine that Cardinal Health had to provide  
20                   effective controls to guard against diversion?

21      **A.**     Yes.

22      **Q.**     And did that involve physical security measures?

23      **A.**     Yes.

24      **Q.**     Did it involve suspicious order reporting?

25      **A.**     Yes.

1       **Q.** Now, the physical security measures we haven't talked  
2 about much. But at a high level, what did the regulations  
3 require?

4       **A.** The regulations on physical security are rather  
5 extensive I think is a good word there. There's, there's  
6 the amount of rebar that has to be in the concrete and how  
7 wide the, the cage has to be -- it has to be set -- and who  
8 can have access to the cage and vault.

9                  Those, those physical security requirements -- the  
10 cameras that you have to have. You know, there's a lot of  
11 extensive regulations on physical security.

12       **Q.** So there's a lot of details built into those  
13 regulations?

14       **A.** Oh, yeah.

15       **Q.** Now, as to the suspicious order reporting requirement,  
16 what did the regulations require?

17       **A.** The suspicious order -- it's a fairly small section  
18 that says that, that upon discovery, the, the -- you must,  
19 you must -- and I'm probably going to get this wrong --  
20 design and implement the system to identify to the  
21 registrants suspicious orders of controlled substances. It  
22 was maybe 60 words and that's it.

23       **Q.** Now, did Cardinal Health report suspicious orders not  
24 just to the DEA but any other state regulatory body in West  
25 Virginia?

1       **A.** Yes, to the Board of Pharmacy.

2       **Q.** And do you have any understanding of what the DEA did  
3                   with the suspicious order report?

4       **A.** I do not.

5       **Q.** Did the regulations specify what must be included in a  
6                   Suspicious Order Monitoring System?

7       **A.** No, it doesn't.

8       **Q.** Your SOM system that you helped put together, Mr. Mone,  
9                   did you come up with SOPs, Standard Operating Procedures,  
10                  related to various parts of the system?

11      **A.** Yes, SOPs were created.

12      **Q.** And why did you create SOPs?

13      **A.** The, the rationale for creating an SOP is to both  
14                  create a framework within which all the employees know what  
15                  to expect and it forms the basis for, if you will, training  
16                  new employees in the areas that they're going to be engaged.

17      **Q.** I'm going to try to run through -- get a couple of SOPs  
18                  in here quickly. Cardinal 1. Mr. Mone, could you tell us  
19                  what Cardinal 1 is?

20      **A.** It is the SOP for a new retail independent customer  
21                  survey process.

22      **Q.** And if you could continue to keep your voice up, sir.

23      **A.** Okay. I'm sorry.

24      **Q.** If you turn to the last page, you're listed as the  
25                  owner of the document. What does that mean?

1       **A.**    It means that I was the last person to review the  
2           document before it went over to be approved and entered into  
3           the, for lack of a better term, the SOP system.

4       **Q.**    And, to the best of your knowledge, were these  
5           procedures followed at Cardinal Health?

6       **A.**    Yes, they were.

7       **Q.**    Let me put in front of you --

8                  MS. MAINIGI: Your Honor, actually could I go  
9           ahead and move into evidence Cardinal Exhibit 1?

10                 MR. FULLER: No objection, Judge.

11                 THE COURT: It's admitted.

12                 MS. MAINIGI: Thank you, Your Honor.

13                 Could I get Cardinal 30, please.

14       BY MS. MAINIGI:

15       **Q.**    Could you identify Cardinal 30 for the record,  
16           please, Mr. Mone?

17       **A.**    It is the SOP for the new account approval process.

18       **Q.**    And did you assist with putting this SOP together?

19       **A.**    I was an approver of this.

20       **Q.**    And what was the purpose of this SOP?

21       **A.**    In a similar way, it sets the framework for how folks  
22           are supposed to operate.

23       **Q.**    And who implemented the procedures in this SOP?

24       **A.**    That would have been the KYC individuals.

25                  MS. MAINIGI: Could I get Cardinal 745, please.

1           And, Your Honor, I'd like to move into evidence while  
2 we're waiting Cardinal 30.

3           THE COURT: Is there any -- you're moving into  
4 evidence 30?

5           MS. MAINIGI: Yes, Your Honor.

6           THE COURT: Is there any objection to 30?

7           MR. FULLER: No, Your Honor.

8           THE COURT: It's admitted.

9           THE WITNESS: May I amend my last statement?

10          BY MS. MAINIGI:

11          **Q.** Yes, please.

12          **A.** Not only was it our SOM people, but because this had to  
13 do with the, the database, this also applied to the  
14 individuals that maintained the database of customers.

15          **Q.** Thank you, Mr. Mone.

16          Please take a look at Cardinal 745. And could you  
17 identify this SOP for us, please?

18          **A.** This is the process to establish SOM threshold limits.

19          **Q.** And did you help put this together as well?

20          **A.** To the best of my recollection, I participated.

21          **Q.** And do you know who else assisted in putting this  
22 together?

23          **A.** It would have been the analytics people.

24          **Q.** And this is the process followed by who to set  
25 thresholds?

1       **A.**   It is the framework and methodology when formulating  
2 thresholds by the analytics people and, of course, the  
3 pharmacists.

4       **Q.**   And, to the best of your knowledge, were these  
5 procedures followed at Cardinal Health to set thresholds?

6       **A.**   To the best of my knowledge, they were.

7                  MS. MAINIGI: Your Honor, I'd like to move in  
8 Cardinal 745, please.

9                  THE COURT: Any objection to 745?

10                 MR. FULLER: No, Your Honor.

11                 MS. MAINIGI: Could I have Cardinal --

12                 THE COURT: It's admitted.

13                 MS. MAINIGI: Thank you, Your Honor.

14 BY MS. MAINIGI:

15       **Q.**   Cardinal 743. Could you identify that, please, Mr.  
16 Mone?

17       **A.**   It is the SOP for threshold event review,  
18 self-verification; decision making and threshold outcome  
19 communication.

20       **Q.**   So the last SOP related to setting the threshold. What  
21 related to the threshold does this SOP cover?

22       **A.**   This covers the rest of the story with regard to what  
23 is done with reports.

24       **Q.**   And, so, does this cover what happens if something  
25 kicks out of a threshold analysis or review?

1       **A.**     Yes, it does.

2       **Q.**     Does it -- is it one of the tools that gets used to  
3              help determine whether an order is reported as suspicious or  
4              not?

5       **A.**     Yes, it does.

6       **Q.**     And, to your knowledge, were these -- was this SOP  
7              followed at Cardinal?

8       **A.**     To the best of my knowledge, yes.

9                  MS. MAINIGI: Your Honor, I'd like to move for the  
10                 admission of 743.

11                 THE COURT: Any objection to 743?

12                 MR. FULLER: No objection.

13                 MR. ACKERMAN: No objection.

14                 THE COURT: It's admitted.

15         BY MS. MAINIGI:

16       **Q.**     Now, Mr. Mone, was there any involvement by the  
17              sales department in the threshold event review process?

18       **A.**     No.

19                  MS. MAINIGI: May I ask for Cardinal 740, please.

20         BY MS. MAINIGI:

21       **Q.**     Coming back on sales for a moment while we hand  
22              this out, so sales, the sales staff did not participate  
23              in setting customer thresholds?

24       **A.**     They did not.

25       **Q.**     Did sales staff participate in raising or lowering

1 thresholds?

2 **A.** No, they did not.

3 **Q.** Did sales staff participate in evaluating individual  
4 pharmacy orders?

5 **A.** No, they did not.

6 **Q.** Were sales staff part of any decision about whether an  
7 order would be reported to DEA as suspicious?

8 **A.** No, they were not.

9 **Q.** Can you identify Cardinal 740, please?

10 **A.** It is the SOP for detecting and reporting suspicious  
11 orders and responding to threshold events.

12 **Q.** Is this an updated SOP?

13 **A.** It is.

14 MS. MAINIGI: Your Honor, I'd like to move for the  
15 admission of Cardinal 740.

16 THE COURT: Any objection to 740?

17 MR. FULLER: No, Your Honor.

18 MR. ACKERMAN: No.

19 THE COURT: It's admitted.

20 BY MS. MAINIGI:

21 **Q.** I'm going to put, Mr. Mone, Cardinal 26 in front of  
22 you in a moment. Can you identify Cardinal 26 for us,  
23 please?

24 **A.** It is the on-site investigations SOP.

25 **Q.** And what does this SOP cover generally?

1       **A.**     The guidance on -- in outlining the steps involved in  
2 conducting on-site investigations.

3       **Q.**     So investigators would know to follow this SOP in terms  
4 of what to look for when they were on-site?

5       **A.**     Yes, they would.

6       **Q.**     And, to your knowledge, was, was this SOP followed at  
7 Cardinal?

8       **A.**     To the best of my knowledge, it was.

9                  MS. MAINIGI: I'd like to move for the admission  
10 of Cardinal 26, please.

11                 THE COURT: Any objection to 26?

12                 MR. FULLER: No, objection.

13                 MR. ACKERMAN: No, Your Honor.

14                 THE COURT: It's admitted.

15 BY MS. MAINIGI:

16       **Q.**     Mr. Mone, I've put Cardinal 747 in front of you.  
17 Can you identify this SOP, please?

18       **A.**     It is an on-site investigations SOP.

19       **Q.**     And how does it relate to the last SOP we just looked  
20 at?

21       **A.**     This is an update.

22       **Q.**     And, so, these SOPs were updated periodically?

23       **A.**     Yes, they were.

24       **Q.**     And did you participate in this updating process?

25       **A.**     To the best of my recollection, I did. No, it's in

1           October -- this is '12 -- I don't remember this one.

2       **Q.**   Are you listed as the approver on Page 21?

3       **A.**   Page 21. Oh, sure enough. I must have done it.

4       **Q.**   What's the difference between the approver and the  
5 owner on these SOPs?

6       **A.**   The system -- and, and I don't know the accounting  
7 terms for this. But you're not supposed to have the same  
8 person who does something be the approver of it. And, so,  
9 it's a system whereby one person writes it and prepares it  
10 and another person approves it.

11      **Q.**   So it's a checks and balances?

12      **A.**   Yeah. And then the, the approver -- once the approver  
13 approves it, it gets entered into the system.

14      **Q.**   To your knowledge, was this SOP followed at Cardinal?

15           MR. FULLER: Your Honor, objection. There hasn't  
16 been a proper foundation. This witness has testified he  
17 doesn't even recall this SOP.

18           THE COURT: I think he changed his mind and said  
19 he did.

20           THE WITNESS: I did, yeah. I'm sorry. I  
21 apologize.

22           MR. FULLER: He said he didn't remember it. His  
23 name's on it.

24           THE COURT: Well, and then he --

25           Do you remember it?

1                   THE WITNESS: Do I, do I remember this with the  
2 specificity that I do other things? No, I don't. But,  
3 undoubtedly, in order for this to have gotten in, I would  
4 have at the time had to have been able to do it.

5                   THE COURT: Okay. Objection is overruled.

6                   MR. ACKERMAN: Your Honor, apologies. I'd also  
7 offer an objection on the grounds that the time frame -- the  
8 question was, was this standard operating procedure  
9 followed. And the witness has testified that during the  
10 time frame following the standard operating procedure he  
11 wasn't responsible for QRA I thought unless I'm  
12 misremembering the testimony.

13 BY MS. MAINIGI:

14 **Q.** When did you stop heading up Anti-Diversion in  
15 2012?

16 **A.** September.

17 **Q.** This is dated April?

18 **A.** I apologize for creating the confusion. It was -- it's  
19 a long day.

20 **Q.** Until at least you left Anti-Diversion, do you have any  
21 reason to believe that this SOP was not followed?

22 **A.** No.

23                   MS. MAINIGI: Your Honor, I'd like to move for the  
24 admission of Cardinal 747, please.

25                   THE COURT: Is there any objection to it now?

1 MR. ACKERMAN: No objection.

2 THE COURT: Mr. Fuller?

3 MR. FULLER: No, Your Honor.

4 THE COURT: Admitted.

5 BY MS. MAINIGI:

6 **Q.** Mercifully we're done with the SOPs.

7 If I could shift your attention to chain pharmacies  
8 because I think you got a few questions about chain  
9 pharmacies from Mr. Fuller. Do you recall that?

10 **A.** Yes, I do.

11 **Q.** What chain pharmacies do you recall Cardinal Health  
12 supplying?

13 **A.** We had chain pharmacies like Kroger and, and mostly,  
14 and most -- to the best of my recollection, most all of  
15 their banners. There's Kroger and then there's like 20  
16 different kind of grocery stores underneath them. We had  
17 CVS. We had -- and some regional, some smaller regional  
18 chains.

19 **Q.** Did you ever have Walgreens?

20 **A.** For a period of time we did.

21 **Q.** Safeway? K-Mart?

22 **A.** Safeway we did. K-Mart, yes, K-Mart we did as well.

23 **Q.** And did -- we looked at the three components of the  
24 Cardinal Health system -- do you recall that?

25 **A.** I do.

1       **Q.** -- on the screen. Did Cardinal Health's Electronic  
2       Monitoring System apply in the same way to chains and retail  
3       independents?

4       **A.** It did.

5       **Q.** Were there any differences in the way that the SOM  
6       process dealt with chain pharmacies as compared to  
7       independent retail pharmacies?

8       **A.** Only to the extent of where we obtained our  
9       information.

10      **Q.** Can you describe that to me, please?

11      **A.** Well, given, given the chain structure, instead of --  
12       in a, in a retail pharmacy we would go to that independent  
13       retail pharmacy to get the information. In the chain  
14       structure, we went to the chain folks to get information.

15      **Q.** Why would you do it that way for the chain?

16      **A.** Well, that's where the information is. That's where  
17       the information can be collected. And that was the most  
18       efficient way of getting that information, as well as  
19       providing a circumstantial guarantee that the information  
20       was accurate because the data that we were looking for would  
21       be housed centrally as opposed to trying to get it at a  
22       chain, at an individual store level. They were able to get  
23       it to us easier.

24      **Q.** The chain pharmacies generally maintained the type of  
25       information you were looking for at their corporate

1 location?

2 **A.** Yes.

3 **Q.** Now, do you recall, Mr. Mone, whether there was any  
4 guidance from DEA as to whether chain pharmacies should be  
5 treated the same or different than retail independents?

6 **A.** No, I don't recall that.

7 **Q.** Were chains assigned customized thresholds for all  
8 controlled substances like other customers were?

9 **A.** Yes, they were.

10 **Q.** Did the Cardinal Anti-Diversion team apply the same  
11 standard in their review of threshold events for chain  
12 pharmacies in the same way that they did for other  
13 customers?

14 **A.** Yes, they did.

15 **Q.** Did your team, to your knowledge, ever lower the  
16 thresholds for chain stores?

17 **A.** Yes. In fact, we raised and lowered thresholds for all  
18 of our customers based upon the totality of the  
19 circumstances and the analysis that we made.

20 **Q.** And the manner in which you did that, was that  
21 consistent with how it was done for independents?

22 **A.** Yes.

23 **Q.** In addition to training your employees on  
24 Anti-Diversion, did Cardinal Health talk to its customers  
25 about Anti-Diversion?

1       **A.**    Yes.

2       **Q.**    I'm going to ask for Cardinal 458, please.

3                  After you've had a chance to look at it, Mr. Mone,  
4                  could you identify Cardinal 458, describe what it is?

5       **A.**    It is a, it is a correspondence between Cardinal Health  
6                  and our customers that included a, an article that was  
7                  commissioned by two pharmacists -- written by two pharmacist  
8                  attorneys as an education piece about understanding the  
9                  pharmacist corresponding -- well, in this instance,  
10                 corresponding responsibility, yeah.

11      **Q.**    And you described corresponding responsibility before?

12      **A.**    I did.

13      **Q.**    What was the purpose, to your understanding, of sending  
14                 this communication to customers?

15      **A.**    Just as we would provide continuing education for  
16                 pharmacists at state, local, and national meetings, we  
17                 wanted to deliver, we wanted to deliver information to  
18                 customers to remind them of their obligations with regard to  
19                 the dispensing of controlled substances pursuant to  
20                 prescriptions that were written.

21      **Q.**    You mentioned continuing pharmacy education at various  
22                 meetings. Can you give me a little bit more flavor of that?

23      **A.**    Well, often times we would be either invited -- almost  
24                 always it's invited. I don't recall ever asking to speak.  
25                 But we would have invitations to speak and provide -- just

1 like we have CLE, there's continuing pharmacy education for  
2 pharmacist programs. And we would, we would present those  
3 at state and national pharmacy meetings.

4 **Q.** And why was correspondence like this, or attending  
5 those pharmacy events so important?

6 **A.** Again, it goes back to my philosophy that  
7 Anti-Diversion is everyone's responsibility. And because  
8 they are our customers, we want to educate our customers in  
9 the best manner that we can so that they're doing the right  
10 things; that they're aware of doing the right things.

11 MS. MAINIGI: Your Honor, I'd like to move for the  
12 admission of Cardinal 458, please.

13 THE COURT: Any objection to 458?

14 MR. FULLER: No objection, Judge.

15 MR. ACKERMAN: No objection.

16 THE COURT: 458 is admitted.

17 MS. MAINIGI: Can I get Cardinal 765, please?

18 BY MS. MAINIGI:

19 **Q.** Now, plaintiffs' counsel asked you, Mr. Mone, a few  
20 questions about Medicine Shoppe. Do you remember that?

21 **A.** I do.

22 **Q.** Specifically, a Medicine Shoppe pharmacy I think called  
23 T & J Enterprises located in Huntington. And what I've put  
24 in front of you, Cardinal 765, is a document related to that  
25 pharmacy. Could you identify what it is for us, please?

**A.** It is a Retail Pharmacy Self-Questionnaire.

2 Q. And this was submitted by the Medicine Shoppe in  
3 February of 2008?

4           **A.** Yes, it was.

5 Q. And this is the type of questionnaire that you walked  
6 through with us earlier; is that right?

7           **A.**       Yes.

8 MS. MAINIGI: Your Honor, I'd like to move into  
9 evidence Cardinal 765.

10 THE COURT: Any objection to 765?

11 MR. FULLER: No objection, Your Honor.

12 MR. ACKERMAN: No objection.

13 THE COURT: All right, it's admitted.

14 BY MS. MAINIGI:

15 Q. Let's take a look at Question 22 of the document,  
16 Mr. Mone.

17 | A. Okay.

18 Q. Did the pharmacy sign a compliance agreement requiring  
19 it to adhere to all rules and regulations regarding  
20 diversion?

21 | A. Yes.

22 Q. And let's look at 23 and 24. Does Cardinal ask about  
23 the history with the DEA in these questionnaires?

24           **A.**      It did.

25 Q. And it asks whether there's been a suspension or

1 revocation?

2 **A.** It did.

3 **Q.** And how about 39? What does 39 show?

4 **A.** Question 39 asks about the pain management clinics and  
5 nursing homes and long-term care facilities or hospices that  
6 the pharmacy may supply, provide prescriptions for.

7 **Q.** And why is this type of question important to ask?

8 **A.** It's an important question to ask to know your customer  
9 and to know and understand the scope of what their likely  
10 controlled substance use would be.

11 THE COURT: How often did you have these filled  
12 out by the pharmacies?

13 THE WITNESS: These were filled out by the  
14 pharmacy on paper initially, then electronically after  
15 threshold events.

16 THE COURT: And how often were they done?

17 THE WITNESS: They were done periodically. There  
18 was no set schedule to it.

19 THE COURT: Okay.

20 BY MS. MAINIGI:

21 **Q.** And then there was a questionnaire that was done at  
22 the beginning before a pharmacy was on board; correct?

23 **A.** Correct.

24 **Q.** But this is one that just came up periodically, so you  
25 had two different types of questionnaires?

1       **A.** Yeah. They had -- essentially, the same questions were  
2 being asked because you would be able to then look at the  
3 changes that were made from questionnaire to questionnaire.

4       **Q.** Now, after the pharmacy provides this type of  
5 information, does Cardinal Health verify it?

6       **A.** To the extent that we were able to verify the  
7 information from objective sources, yes. And when a site  
8 visit was conducted, the investigator would continue to  
9 question to determine as best he or she could the validity  
10 of the answers.

11      **Q.** Okay. Let's take a look at Cardinal 763, please. I'm  
12 going to hand to you an example of the threshold event  
13 review process, Mr. Mone. Can you describe what this is a  
14 snapshot of, please?

15      **A.** This is a snapshot of the Anti-Diversion Customer  
16 Profile that formed the basis of the, the review by the  
17 pharmacist of an order that did a threshold for a specific  
18 customer.

19      **Q.** So this is one of the screens that the pharmacist might  
20 look at when something is kicked out for threshold review?

21      **A.** Yes, it would be.

22      **Q.** And this particular one that's in front of you, is this  
23 for T & J Enterprises that we were just talking about?

24      **A.** It is.

25      **Q.** And is this, is this called the ADC profile?

1       **A.**    It is.

2       **Q.**    And explain that profile to us, please.

3       **A.**    So in, in a -- in the process of continuous  
4       improvement, we started out with a paper system and files.  
5       And my vision was to have ADC, Anti-Diversion  
6       Centralization. I wanted to have the disparate systems that  
7       existed that the pharmacist had to go to to collect and  
8       collate all of the information into one spot so that it was  
9       easier for them to consume and would drive efficiency.

10           And this is one iteration of that continuous  
11       improvement of driving toward, having the pharmacist and the  
12       team be able to consume information and make decisions and  
13       record those decisions.

14       **Q.**    What sort of type of information is available here?

15       **A.**    On the form you have the DEA license information.

16       You've got the customer information. You've got a purchase  
17       profile which gives you a broader sense of the pharmacy, not  
18       just the controlled substances. You have the SOM event  
19       specific information. And for that drug family you have the  
20       historical purchase data.

21           MS. MAINIGI: Your Honor, I'd like to move for the  
22       admission of Cardinal 763, please.

23           THE COURT: Any objection to 763?

24           MR. FULLER: No, Your Honor.

25           MR. ACKERMAN: No objection.

1                   THE COURT: It's admitted.

2                   MS. MAINIGI: May I have Plaintiffs' 2020, please.

3                   Any objection to admitting Plaintiffs' 2020?

4                   MR. ACKERMAN: I'm still reviewing it, but it  
5 looks like hearsay.

6                   MS. MAINIGI: Let's go through it. I don't want  
7 to put it up on the screen.

8 BY MS. MAINIGI:

9                   **Q.** Mr. Mone, if you could turn to the second page,  
10 it's an email. Does this look like the email that was  
11 shown to you earlier by Mr. Fuller specifically as it  
12 relates to T & J Enterprises, Medicine Shoppe in  
13 Huntington, West Virginia? Remember there was a black  
14 hole email --

15                   **A.** Yes.

16                   **Q.** -- and you talked about this earlier?

17                   **A.** Page 2 does appear to be that, the content of that  
18 prior document.

19                   **Q.** And I think what he didn't show you is the follow-on  
20 email from Mr. Quintero. If you could take a look here and  
21 then let me know what you understood the response was from  
22 Mr. Quintero.

23                   **A.** So what I, what I note from the email is that Gilberto  
24 was responding to Doug Linden and cc'd Chris and myself on  
25 his phone that as the, as the SVP of the organization that

1       he will revisit the pharmacies mentioned and respond to  
2 Doug's concern.

3       **Q.**     So some pharmacies were identified and Mr. Quintero  
4 said that there would be follow-up done at these pharmacies.  
5 Is that fair?

6       **A.**     That's correct. We'll revisit the pharmacies mentioned  
7 in the email.

8       **Q.**     Now, was it your understanding that, in fact, the store  
9 was visited after this email?

10      **A.**     I have no recollection as to whether or not the  
11       pharmacy was visited after this email.

12      **Q.**     Do you have any reason to believe that it was not  
13       visited?

14      **A.**     I have no reason to believe either way that it was or  
15       it was not.

16                  MS. MAINIGI: Your Honor, at this time I would  
17       like to move for the admission of P-2020.

18                  THE COURT: Any objection to 2020?

19                  MR. ACKERMAN: No objection, Your Honor.

20                  MR. FULLER: No, Your Honor.

21                  THE COURT: It's admitted.

22       BY MS. MAINIGI:

23       **Q.**     Now, with respect to 2020, the timing of this email  
24       chain is approximately June, 2012; is that right?

25       **A.**     That is correct.

1       **Q.**   All right. Let's take a look at Cardinal 770.

2                  Can you identify Cardinal 770, Mr. Mone, after you've  
3                  had a chance to review it?

4       **A.**   It is the, the -- it is the, the representation of the  
5                  computer investigator site visit report.

6       **Q.**   And the investigator site visit report for where?

7       **A.**   T & J Enterprises.

8       **Q.**   And is that the T & J Enterprises in Huntington, West  
9                  Virginia?

10      **A.**   Yes, it is. It's the same, it's the same address that  
11                  we've been talking about.

12      **Q.**   And what was the date of the visit?

13      **A.**   The 20th of August of 2012.

14      **Q.**   And when were -- when was that discussion internally at  
15                  Cardinal about T & J?

16      **A.**   June 12th.

17      **Q.**   2012?

18      **A.**   2012, yes.

19      **Q.**   So within two months, the visit had been made?

20      **A.**   Yes.

21      **Q.**   Okay.

22                  MS. MAINIGI: Your Honor, at this point I'd like  
23                  to move for the admission of Cardinal 770.

24                  THE COURT: Any objection to 770?

25                  MR. FULLER: No, Your Honor.

1 MR. ACKERMAN: No, Your Honor.

2 THE COURT: It's admitted.

3 BY MS. MAINIGI:

4 **Q.** Mr. Mone, does Cardinal Health see individual  
5 prescriptions?

6 **A.** It does not.

7 **Q.** Does Cardinal Health assess patient health information  
8 with doctors?

9 **A.** No, it does not. It doesn't have any PHI to, to  
10 communicate with them.

11 **Q.** And does Cardinal Health receive information about  
12 patients from pharmacies?

13 **A.** No, unless -- if they did, it would be a big -- it  
14 would be a HIPAA violation.

15 **Q.** Does Cardinal Health have access to the complete  
16 ordering history of pharmacies if they order from multiple  
17 distributors?

18 **A.** No, it would not.

19 **Q.** Who has that information?

20 **A.** The DEA would have that information.

21 **Q.** During your time at Cardinal from 2008 to 2012 did you  
22 regularly interact with the DEA?

23 **A.** I did.

24 **Q.** Did Cardinal Health request information about its  
25 customers from the DEA?

1       **A.**    We did.

2       **Q.**    Did Cardinal Health request ARCos information from the  
3           DEA?

4       **A.**    Yes, we did.

5       **Q.**    Why?

6       **A.**    Well, if you go back to the question you asked about  
7           who can see all of the data when there are multiple  
8           suppliers, there is a point in time when we requested the  
9           ARCos data so that we would know not, not the "who" of the  
10          other suppliers, just the "what" and the volume of the  
11          "what" so that we could add that into our evaluation about  
12          the customer.

13      **Q.**    Cardinal Health wanted to integrate into its evaluation  
14          process how much other distributors were sending to a  
15          particular pharmacy. Is that fair?

16      **A.**    Yeah, the rest of the story.

17      **Q.**    Did the DEA provide that information?

18      **A.**    They did not.

19      **Q.**    Why not?

20      **A.**    To the best of my recollection, they claimed it was  
21          proprietary information.

22      **Q.**    Did Cardinal just ask for that information once or  
23          multiple times?

24      **A.**    Multiple times.

25      **Q.**    Did Cardinal Health also ask the DEA to provide it with

1       any information that the DEA possessed indicating that any  
2       Cardinal Health customer was engaged in diversion so that  
3       Cardinal could cease distributing controlled substances to  
4       that customer?

5       **A.**     To the best of my recollection, that was in a request  
6       to DEA.

7       **Q.**     And did the DEA agree to let you know if it was aware  
8       of Cardinal Health's customers engaged in diversion?

9       **A.**     I -- to the best of my recollection, I don't recall  
10      that there ever was a response to that request.

11      **Q.**     We've talked a lot today about Cardinal Health SOM  
12      system and its components. Did Cardinal Health share the  
13      details about its Anti-Diversion system with the DEA?

14      **A.**     Yes, it did.

15      **Q.**     On more than one occasion?

16      **A.**     More than one occasion.

17      **Q.**     As part of that effort did you meet in early 2009 with  
18      Barbara Boockholdt of the DEA?

19      **A.**     I did.

20      **Q.**     And remind us, who is Barbara Boockholdt?

21      **A.**     Barbara Boockholdt was -- maybe she was Chief of  
22      Regulatory, or she was Chief of the Policy Section at DEA  
23      and was our contact at DEA, at DEA headquarters.

24      **Q.**     So this early 2009 meeting, describe that to me.

25      **A.**     The early 2009 meeting was about -- I'd say it was

1 almost a week.

2 **Q.** The meeting was a week?

3 **A.** Pardon?

4 **Q.** The meeting was a week?

5 **A.** Yeah, more than, you know, I think approximately a  
6 week. Barbara and several other DEA diversion investigators  
7 came in to review our system.

8 **Q.** What do you mean by came in to review your system?

9 **A.** They came into Dublin and we sat downstairs in a, in a,  
10 in a room, in a meeting room and we went through our SOM  
11 system.

12 **Q.** And did that involve reviewing the SOPs and other  
13 policies related to the SOM system?

14 **A.** Yes, it did.

15 **Q.** Like the policies we looked at earlier today?

16 **A.** Yes.

17 **Q.** Did it involve reviewing how Cardinal Health set  
18 thresholds for its customers?

19 **A.** Yes, it did.

20 **Q.** Did you describe to Ms. Boockholdt and her colleagues  
21 how Cardinal Health was identifying and reporting suspicious  
22 orders at that point in time in 2009?

23 **A.** Yes.

24 **Q.** Did Ms. Boockholdt and her colleagues request  
25 particular policies to review as you described the system?

1       **A.** Yes, she did.

2       **Q.** And did you provide those to her?

3       **A.** Yes.

4       **Q.** Were copies provided or she just reviewed them?

5       **A.** She reviewed them. And where, where she requested  
6 information, we prepared them. And the ones that were not  
7 readily available, to the best of my recollection, were put  
8 on a thumb drive and mailed to her.

9       **Q.** Did you show her the reports that the SOM system  
10 generated?

11      **A.** I did.

12      **Q.** Mr. Mone, were you transparent with the DEA about the  
13 way Cardinal's SOM system worked?

14      **A.** Yes, very.

15      **Q.** Did you hold anything back?

16      **A.** No.

17      **Q.** In that early 2009 meeting with Ms. Boockholdt and her  
18 colleagues, did the DEA identify any fault in the way that  
19 Cardinal reported suspicious orders?

20      **A.** No. Barbara nor the team identified or told us -- if  
21 they, if they identified them, they didn't tell us about  
22 them. To the best of my knowledge, they didn't identify  
23 any.

24      **Q.** During your time at Cardinal, were there customers that  
25 Cardinal refused to on-board because of a diversion concern?

1       **A.**    Oh, yes.

2       **Q.**    During your time at Cardinal, did Cardinal ever  
3 terminate customers?

4       **A.**    Oh, yes.

5       **Q.**    And when you terminated a customer, did you also notify  
6 the DEA?

7       **A.**    Yes, we did.

8       **Q.**    Was the DEA aware of the number of suspicious orders  
9 reported by Cardinal in the time frame that you were at  
10 Cardinal Health?

11                  MR. ACKERMAN: Objection, speculation as to the  
12 awareness of the DEA.

13                  THE COURT: Well, do you know the answer to that?

14                  THE WITNESS: Well, what I -- Your Honor, what I  
15 can say is that we submitted them to them. What they did  
16 with them after we submitted them to them, I don't know.

17                  THE COURT: Okay. Overruled.

18                  BY MS. MAINIGI:

19       **Q.**    We've talked a bit about the Cardinal policies. As  
20 to the implementation of those policies, was the DEA  
21 able to see individual customer files?

22       **A.**    Yes, they were.

23       **Q.**    Did the DEA visit distribution centers after this early  
24 2009 meeting that you had?

25       **A.**    Yes, they did, approximately I'd say two months later,

1           within two months.

2       **Q.**    Within two months of this early 2009 meeting they  
3           visited distribution centers?

4       **A.**    They did.

5       **Q.**    Did they tell you they were going to visit?

6       **A.**    Yes. It was part of the MOA that they were going to  
7           conduct on-site visits.

8       **Q.**    Do you know how many visits they conducted?

9       **A.**    They, they conducted, to the best of my recollection,  
10           all of the ones in the MOA except Swedesboro.

11      **Q.**    And were there more than the four in the MOA --

12      **A.**    Yes.

13      **Q.**    -- that they visited?

14      **A.**    Correct.

15      **Q.**    Were they done on different days or all on the same  
16           day?

17      **A.**    All on the same day.

18      **Q.**    Were you at any of the distribution centers that they  
19           conducted a visit to?

20      **A.**    Yes, I was.

21      **Q.**    And, to your recollection, what happened at that visit?

22      **A.**    Well, the, the DEA diversion investigators did a deep  
23           dive into the SOM system and wanted it explained as to how  
24           the system operated, and wanted to know how the compliance  
25           officers and the cage and vault employees were integrated

1       into the system. And they wanted to see SOM reports and  
2       customer due diligence files.

3       **Q.**      Was it your impression that they were looking to verify  
4       the system worked as you had indicated it did?

5       **A.**      Yes. I think it was a verification visit based upon  
6       what Barbara had done for a week to see that it actually did  
7       what we said it did.

8       **Q.**      And in the visits did the DEA request information about  
9       particular customers?

10      **A.**     They did.

11      **Q.**      Did they review due diligence files for those  
12       customers?

13      **A.**     They did.

14      **Q.**      To your recollection, did they offer any criticism of  
15       the due diligence files during those visits?

16      **A.**      To the best of my recollection, during the visit I  
17       participated in, they made no concerns about the due  
18       diligence files that they looked at.

19      **Q.**      To the best of your recollection, did they offer any  
20       comments about how long documentation needed to be held in  
21       due diligence files?

22      **A.**     No, they did not.

23      **Q.**      To your knowledge, has the DEA ever instructed  
24       distributors to maintain information in due diligence files  
25       indefinitely?

1       **A.**     No.

2       **Q.**     What are DEA cyclical inspections?

3       **A.**     So as I testified earlier, and I believe that it's a  
4           three-year registration, the cyclical inspections are the  
5           inspections by DEA within that three-year license window  
6           whereby the DEA diversion investigators come in and go  
7           through the distribution center.

8               They go through their records. They go through the  
9           cage and vault. They request an audit. You know, they  
10          usually have an open inventory that they want to look at and  
11          they want to make sure that all of the, you know -- if the  
12          computer says that you have 5,000 of X, they want to be able  
13          to go onto the shelf and count, and they count up 5,000 of  
14          X. So that's what that cyclical inspection looks like.

15       **Q.**     And during these cyclical inspections by the DEA, did  
16          they have full access to Cardinal's policies and procedures?

17       **A.**     They did.

18       **Q.**     Full access to files about customers including due  
19          diligence?

20       **A.**     Yes. To the extent that they would ask for them, the  
21          team would prepare them and ship them to either the  
22          distribution center or directly to the DEA diversion  
23          investigator.

24       **Q.**     Now, as you updated the SOM system over the course of  
25          your time in the Anti-Diversion at Cardinal, did you keep

1       the DEA updated as to any changes or improvements you were  
2       making?

3       **A.**     Yes, I did.

4       **Q.**     How did you do that?

5       **A.**     I -- sometimes I would just call Barbara and sometimes  
6       I would fly up and show Barbara -- have a meeting with  
7       Barbara, you know, schedule a meeting with Barbara, sit  
8       down, bring my laptop, open up the laptop, show what we were  
9       doing, and have a conversation with Barbara and her team  
10      about the improvements. You know, quite frankly, it was a  
11      continuous policy improvement process I was proud of.

12      **Q.**     Did it matter to you what the DEA thought about what  
13      you were doing?

14      **A.**     Yeah, it did, a lot.

15      **Q.**     Why?

16      **A.**     Well, you saw my career. I'm a public service guy.  
17      This is about a, a -- you know, as I told Mr. Fuller  
18      earlier, you know, what you have is a, is a public health  
19      crisis. And I firmly believe that it's, it's a process  
20      whereby everybody has to participate, you know, within their  
21      lane, what they can do to help do the right thing in their  
22      lane. And I wanted her to know what we were doing.

23                  And I -- you know, quite frankly, I'd known Barbara for  
24      many years and I expected her to tell me -- I expected her  
25      to tell me, you know, "Hey, we don't like what you're doing,

1 change it." And, quite frankly, I would have.

2 **Q.** And did you also communicate with various Boards of  
3 Pharmacy about what you were doing?

4 **A.** Oh, yes.

5 **Q.** Did you communicate with the West Virginia Board of  
6 Pharmacy about suspicious order monitoring?

7 **A.** Yes. I, I -- you went back through my career. As a  
8 former Executive Director of the Board, there's kind of a  
9 relationship between the Executive Directors. And, so, yes,  
10 I communicated not only with the Executive Directors, but  
11 when we talked about the MPJE, when the West Virginia Board  
12 would send inspectors to the MPJE meeting, I would  
13 communicate with them as well there, not just about the  
14 MPJE.

15 **Q.** To your recollection, did you explain the Cardinal  
16 Health Suspicious Order Monitoring System to the West  
17 Virginia Board of Pharmacy?

18 **A.** To the best of my recollection, I did. They knew the  
19 essential parameters of it.

20 **Q.** Did they express any concerns to you?

21 **A.** No, neither -- none of them did.

22 **Q.** And did you tell me earlier that you did -- Cardinal  
23 Health did report suspicious orders to the West Virginia  
24 Board of Pharmacy as well?

25 **A.** Yes, we did.

1 MS. MAINIGI: Your Honor, I, I continue to reserve  
2 my objection on the 2012 settlement. But because Mr. Fuller  
3 asked questions about it, I'll ask a couple as well.

4 THE COURT: All right.

5 BY MS. MAINIGI:

6 **Q.** Describe for me what the 2012 action by DEA against  
7 Cardinal Health involved. What facility?

8 **A.** It involved the Lakeland facility, Lakeland, Florida  
9 facility.

10 **Q.** And did it concern specific pharmacies in Florida?

11 **A.** It did.

12 **Q.** How many?

13 **A.** Four.

14 **Q.** Now, had Barbara Boockholdt made a recommendation to  
15 you for additional due diligence for Cardinal Health  
16 customers in Florida?

17 **A.** She did.

18 **Q.** What was that time period approximately?

19 **A.** I don't recall when she, when she asked me to do that.

20 **Q.** Did she identify any particular customers?

21 **A.** No, she did not.

22 **Q.** Now, the pharmacies that dispense controlled  
23 substances, they're obviously licensed by the DEA; right?

24 **A.** Yes.

25 **Q.** And the DEA can certainly take action against

1 pharmacies; correct?

2 **A.** Yes, they can.

3 **Q.** When Ms. Boockholdt voiced this concern to you, what  
4 did you do?

5 **A.** Well, we were in the process -- you know, obviously the  
6 investigators would have their, their investigative  
7 schedule. And they were scheduled to go down to Florida  
8 anyway, and Vince is from Florida.

9 What we did was we got a team together and we looked at  
10 the data. To the best of my recollection, we took like the  
11 top 50 customers and sent the whole, the whole team down to  
12 Florida to do site visits on, on those Florida customers.  
13 She asked me to do it. I did it.

14 **Q.** Did you continue doing business with all the customers  
15 that you did site inspections on down there?

16 **A.** No, we did not.

17 **Q.** What was the result of the process?

18 **A.** The result of the process was that we determined that  
19 there were -- and I don't remember how many. There were  
20 pharmacies that based upon the site visit reflected a --  
21 reflected a concern about their corresponding meeting and  
22 corresponding responsibility. And, therefore, we made the  
23 decision no longer to conduct business with them.

24 **Q.** And did the Lakeland action involve some pharmacies  
25 that you had already cut off?

1       **A.**     Yes, they did.

2       **Q.**     During the time period that you were head of Cardinal's  
3                   Anti-Diversion system, did you believe that it was  
4                   effective?

5       **A.**     Yes, I, I believe it was -- I don't know that you could  
6                   have very effective, but, yes, it was effective.

7       **Q.**     Did you believe Cardinal Health complied with DEA  
8                   regulations and the Controlled Substances Act?

9       **A.**     Yes, I did.

10      **Q.**     Now, during your time as the head of Cardinal Health  
11                   Anti-Diversion Program, did you ever allow an order to be  
12                   shipped that you believed was going to be used for anything  
13                   other than a legitimate medical purpose?

14      **A.**     No.

15                   MS. MAINIGI: I have no further questions.

16                   THE COURT: Is there going to be any cross of Mr.  
17                   Mone by the other defendants?

18                   MR. HESTER: None from us, Your Honor.

19                   MR. NICHOLAS: No, Your Honor.

20                   THE COURT: How much redirect are you going to  
21                   have, Mr. Fuller?

22                   MR. FULLER: I hope not much, Judge.

23                   THE COURT: Can you do it in seven minutes?

24                   MR. FULLER: We're sure going to try.

25                   THE COURT: Okay. Let's go.

1

## REDIRECT EXAMINATION

2

BY MR. FULLER:

3

**Q.** Mr. Mone, you said just a moment ago that

4

Ms. Boockholdt under your system pointed out issues in  
Florida and you went on down there and you found some  
problems and you cut off pharmacies; right?

7

**A.** When -- I missed some of the beginning part of your  
question.

9

**Q.** I'm sorry. When Ms. Mainigi was asking you about Ms.  
Boockholdt and her telling you about the Florida issue and  
you said that you guys went down to Florida and you cut off  
a bunch of pharmacies; right?

13

**A.** There, there wasn't a Florida issue per se. What  
Barbara said was you should -- she was recommending that you  
go down and look at your Florida customers because of  
Florida being Florida.

17

**Q.** Sure. And your system is the same nationwide, which  
we've already established, and you cut off a bunch of  
Florida customers; correct?

20

**A.** We cut off customers based upon our site visit review,  
yes.

22

**Q.** It was hundreds of customers, wasn't it?

23

**A.** No. We visited, we visited a little more than 50 and  
we cut off -- I don't remember how many, but we -- as a  
result of that visit -- as a result of that effort, I

1       couldn't cut off 100 because we only visited like 53  
2       pharmacies, 53, 54.

3       **Q.**     And, so, the national system, did you then go look  
4       everywhere else to see if you were having the same  
5       deficiencies?

6       **A.**     It wasn't a question of deficiencies in my mind. It  
7       was a question of Barbara telling us to pay particular  
8       attention and focus on Florida.

9                  And the rest of the system, we began to look at the  
10       same types of analyses. But that was a building process  
11       with regard to take those top 50 customers and begin to look  
12       at those as well. But we didn't go into another  
13       jurisdiction and do a deep dive. We relied on the strength  
14       of the system.

15       **Q.**     It's the same system that got the second MOU in 2012;  
16       right?

17       **A.**     The same system that, that the Lakeland ISO occurred  
18       with.

19       **Q.**     And you're aware that Cardinal admitted fault in the  
20       second MOU; correct?

21                  MS. MAINIGI: Objection. The document speaks for  
22       itself.

23                  MR. FULLER: I'm asking if he's aware, Judge.

24                  THE COURT: Overruled. You can answer it.

25                  THE WITNESS: I'm aware that the settlement of the

1       2012 acknowledged that there were some -- it, it was some  
2       orders of -- it was like some orders of some pharmacies was  
3       the best of my recollection of what that MOU said -- MOA  
4       said.

5       BY MR. FULLER:

6       **Q.**   And, now, counsel showed you 770. Do you have that  
7       document?

8       **A.**   Yeah.

9       **Q.**   And if you look at the last page, the increases in  
10      total controlled substances Rx were attributed to the  
11      closing of a local independent pharmacy SafeScript. Right?

12      **A.**   Yes.

13      **Q.**   This Court's heard about SafeScript. It was one that  
14      was raided and shut down by the DEA. And then it goes on to  
15      explain that the customers at Medicine Shoppe grew from  
16      about 1,100 scripts per month to 1,500 because of these  
17      individuals; right?

18      **A.**   It does.

19      **Q.**   It also references that the growth is because of a pain  
20      clinic. Do you see anywhere in this document that it tells  
21      which pain clinic?

22      **A.**   The text is, is blocked out after the second line on  
23      that page, so I can only read the first two lines of it.

24      **Q.**   I agree. I agree. And there's no listing that you saw  
25      in here of the particular prescribers; correct?

1       **A.**     Let me look.

2                     (Pause)

3                     I do not see the -- in this review that I did fairly  
4 quickly, I don't see the name of a prescriber.

5       **Q.**     Now, last issue, Mr. Mone. Let's talk about the  
6 meeting in 2009 with the DEA and the follow-up where you  
7 explained your system. You were talking with Ms. Mainigi  
8 about that; right?

9       **A.**     The, the January or February meeting in 2009, yeah.

10      **Q.**     Yes. And are you -- who was at the meeting again?  
11                     Help me out.

12      **A.**     So it was my team, all of the team that was there, --

13      **Q.**     Yes, sir.

14      **A.**     -- Barbara Boockholdt and, to the best of my  
15 recollection, three DEA diversion investigators.

16      **Q.**     Do you know Jodi Avergun?

17      **A.**     I do know Jodi Avergun.

18      **Q.**     Was she also involved at that time, maybe not that  
19 meeting, but related to this issue of compliance?

20      **A.**     Was she what?

21      **Q.**     Involved related to this issue of compliance?

22      **A.**     Jodi was a -- is an attorney for Cardinal Health. I  
23 don't know that she was, was involved in the relationship of  
24 the meeting that we had with Barbara. I don't recall her  
25 participating.

1                   MR. FULLER: Judge, I would re-move into evidence  
2 Plaintiffs' 9809 which is a document and a letter from  
3 Ms. Avergun that I've shown before. This witness testified  
4 he had no knowledge, but it's a follow-up to the meetings in  
5 early 2009 with the DEA in which Cardinal through their  
6 lawyer --

7                   THE COURT: I don't remember specifically the  
8 exhibit. It's probably up here buried in all this  
9 somewhere.

10                  MR. FULLER: It is, Judge, and that was my last  
11 issue.

12                  THE COURT: I'm not going to be able to see out  
13 here.

14                  MS. MAINIGI: Your Honor, I have a strong  
15 objection to that. As we discussed earlier -- I know it's  
16 been a long day -- 9809 was a letter from Cardinal's outside  
17 counsel, Jodi Avergun, to the DEA related to Valencia,  
18 California. There's nothing that establishes that somehow  
19 this meeting, this general meeting that Mr. --

20                  THE COURT: Well, and I sustained the objection  
21 but said I'd take a look at it and review it, but I'm not  
22 going to admit it now, Mr. Fuller.

23                  MR. FULLER: Fair enough, Judge. We'll put that  
24 on the table for later follow-up.

25                  I don't have any further questions.

1                   THE COURT: Well, you hit the nail on the head,  
2 Mr. Fuller, and you have the Court's appreciation for that.

3                   MR. FULLER: Thank you, Judge.

4                   THE COURT: Now, is there anything else of this  
5 witness?

6                   MS. MAINIGI: No, Your Honor.

7                   THE COURT: May Mr. Mone be excused?

8                   MR. FULLER: Yes, Your Honor.

9                   MS. MAINIGI: Yes, Your Honor.

10                  I think we do have one scheduling issue for after Mr.  
11 Mone's departure.

12                  THE COURT: Mr. Mone, thank you very much. You're  
13 free to go, sir, --

14                  THE WITNESS: Thank you, Your Honor.

15                  THE COURT: -- with our appreciation.

16                  All right, Ms. Mainigi.

17                  MS. MAINIGI: Your Honor, we just wanted to  
18 confirm, so there's no confusion with witnesses tomorrow  
19 morning, the next witness that has been requested and is  
20 scheduled is Mr. Jesse Kave, also a Cardinal Health witness.

21                  We are planning to present him at 9:00 tomorrow morning  
22 at this point given the time that we have here. I just want  
23 to confirm with the plaintiffs where they stand on that  
24 because there's been some talk of Dr. Werthammer, and we've  
25 got Mr. Kave. He's been teed up and on the runway for a few

1 days ready to go, so we'd like to get him up and out.

2 THE COURT: Who are you going to call, Mr.  
3 Farrell?

4 MR. FARRELL: Our intention is to call  
5 Dr. Werthammer at 9:00 and get him on and then call Mr. Kave  
6 afterwards.

7 THE COURT: Is he the one you're trying to get out  
8 of town?

9 MS. MAINIGI: Mr. Kave, yes.

10 THE COURT: You want to call him first?

11 MS. MAINIGI: That's what we were told was going  
12 to happen. I've tried having a conversation with Mr.  
13 Farrell about this to see if we can try to accommodate him,  
14 but I think Mr. Kave will be very short so we ought to be  
15 able to get him on and off I would assume.

16 MR. FARRELL: Mr. Kave lives in Hurricane, so he's  
17 nearby. Dr. Werthammer is in Huntington.

18 And, so, based upon the way the schedule has been  
19 going, when we do our directs there is extensive redirect.  
20 And I want to make sure Dr. Werthammer gets on and off  
21 tomorrow morning first and then we'll call Mr. Kave.

22 THE COURT: Well, it's your case and I think you  
23 have the right to call them in the order you want to call  
24 them.

25 Does that answer your question, Ms. Mainigi?

1                   MS. MAINIGI: Not quite, Your Honor. I do think  
2 that Mr. Farrell has an obligation to at least call the  
3 witnesses in the order that he represented he was going to.

4                   We are willing to accommodate a later start for Mr.  
5 Kave, but we insist that he not be carried over the weekend.  
6 That, that is just a bridge too far.

7                   So if Mr. Farrell can represent that they can be done  
8 with Mr. Kave tomorrow, then that's fine. But, otherwise,  
9 we want Mr. Farrell to live up to the representations he's  
10 been making to us all week about when Mr. Kave would be  
11 called, which is right after Mr. Mone.

12                  THE COURT: What's the problem with holding him  
13 over if we don't get him finished tomorrow?

14                  MS. MAINIGI: Your Honor, he is a former employee.  
15 He is not someone who is really under the company's control  
16 as a former employee. And it's been represented to us --  
17 originally he was supposed to go on Wednesday, then  
18 Thursday. And now we have been assuming this entire time  
19 that he would be up and out on Friday.

20                  So Mr. Werthammer is the plaintiffs' witness. Again,  
21 we're willing to work with Mr. Farrell but, but he's got to  
22 then either put Mr. Kave up first and whatever happens  
23 happens on time, but you can't ask a former employee who's  
24 been waiting to testify for days to, to then sit patiently  
25 by while they put up another witness when they have

1 previously requested him to appear right after Mr. Mone.

2 THE COURT: Mr. Farrell.

3 MR. FARRELL: I don't have anything pleasant in  
4 response, Judge.

5 THE COURT: Well, Mr. Kave is under subpoena,  
6 isn't he?

7 MR. FULLER: Yes, Your Honor.

8 MS. MAINIGI: I will accept that representation,  
9 Your Honor.

10 THE COURT: Well, I'm going to let the plaintiffs  
11 put their case on in the order they want to put it on. And  
12 I'm sorry if we inconvenience this fellow, but that's just  
13 part of the game, making people wait.

14 MS. MAINIGI: Your Honor, I, I don't -- I  
15 understand and I understand your ruling and, of course,  
16 we'll abide by it. But he's a former employee. They have  
17 said they were going to work with us on scheduling. They've  
18 given us representations on scheduling. So I ask that at  
19 the very least that they make every effort to get him on and  
20 off tomorrow.

21 THE COURT: How long is Mr. Werthammer going to  
22 take?

23 MR. FARRELL: I plan on being less than an hour.

24 THE COURT: Well, let's leave the order the way  
25 the plaintiffs want to do it and we'll see where we go

1 tomorrow. I don't think it's my province to interfere  
2 unduly with the order of evidence the plaintiffs choose to  
3 present. Now, I know there's special circumstances where I  
4 might have an obligation to change that, but that's the way  
5 we'll leave it for tonight.

6 MS. MAINIGI: Thank you, Your Honor.

7 THE COURT: Okay. Is there anything else today?

8 (No Response)

9 THE COURT: Everybody looks tired and ready to go.  
10 Okay. I'll see everybody at 9:00 in the morning.

11 (Trial recessed at 5:07 p.m.)

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## 1 CERTIFICATION:

2 I, Ayme A. Cochran, Official Court  
3 Reporter, and I, Lisa A. Cook, Official Court Reporter,  
4 certify that the foregoing is a correct transcript from  
5 the record of proceedings in the matter of The City of  
6 Huntington, et al., Plaintiffs vs. AmerisourceBergen  
7 Drug Corporation, et al., Defendants, Civil Action No.  
8 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as  
9 reported on May 20, 2021.

10

11

S\Ayme A. Cochrans\Lisa A. Cook

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Reporter

Reporter

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May 20, 2021

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Date

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